UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HECTOR VALDES and HECTOR J. VALDES, individually and on behalf of all those similarly situated, Plaintiff, v. SANOFI-AVENTIS U.S., LLC, NOVO NORDISK INC., and ELI LILLY AND COMPANY, Defendants.	Civil Action No. **COMPLAINT and DEMAND FOR JURY TRIAL**

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Plaintiffs Hector Valdes and Hector J. Valdes ("Plaintiffs") file this civil action, on behalf of themselves and a class of those similarly situated ("Class" as defined below) against defendants Sanofi-Aventis U.S., LLC ("Sanofi"), Novo Nordisk Inc. ("Novo Nordisk"), and Eli Lilly and Company ("Eli Lilly") (collectively, "Defendants") and based upon personal knowledge, information, belief, and investigation of counsel, specifically alleges as follows.

INTRODUCTION

1. Over 29 million people, 9.3% of the country, live with diabetes.[1] A life-threatening disease, many of those with diabetes rely on daily insulin treatments to survive. Interruptions to these regimes can have severe consequences, including sustained damage to the kidneys, heart, nerves, eyes, feet, and skin. Indeed, diabetes is the leading cause of kidney failure, adult-onset blindness, and lower-limb amputations in the United States.[2]

2. Defendants manufacture insulin used to treat diabetes. Over the course of the last five years, each has raised the publicly-reported, benchmark prices of their respective drugs in an astounding and inexplicable manner. Drugs that used to cost $25 per prescription now cost between $300 and $450 dollars. And in the last five years alone, Sanofi, Novo Nordisk, and Eli Lilly have raised their benchmark prices by over 150%. Some patients now pay almost $900 dollars per month just to obtain the insulin drugs they need to survive.

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[1] *Statistics About Diabetes*, American Diabetes Association (May 18, 2015), http://www.diabetes.org/diabetes-basics/statistics/.

[2] *Chronic Disease Prevention and Health Promotion: Diabetes*, Centers for Disease Control Prevention (July 25, 2016), https://www.cdc.gov/chronicdisease/resources/publications/aag/diabetes.htm.

3. The impact of these price increases is such that in February 2016, the NEW YORK TIMES published an op-ed written by an endocrinologist, with the headline "**Break Up the Insulin Racket**," citing some disturbing statistics:[3]

> What makes this so worrisome is that the Big Three have simultaneously hiked their prices. From 2010 to 2015, the price of Lantus (made by Sanofi) went up to 168 percent; the price of Levemir (made by Novo Nordisk) rose by 169 percent; and the price of Humulin R U-500 (made by Eli Lilly) soared by 325 percent.

4. Why has the price of insulin gotten so out of control? Although drug companies usually rely on their research and development costs to rationalize their high drug prices, the manufacturers of insulin admit that their price hikes are unrelated to any jump in production or research and development costs. Instead, these increased benchmark prices are the result of a scheme and enterprise among each Defendant and several bulk drug distributors. In this scheme, the Defendant drug companies set two different prices for their insulin treatments: a publicly-reported benchmark price—also known as the "sticker" price—and a lower, real price that they offer to certain bulk drug distributors.

5. The most important of these bulk drug distributors are entities known as pharmacy benefit managers ("PBMs").

6. Business is booming for PBMs. Together, the three biggest benefit managers—Express Scripts, CVS Health, and OptumRx—bring in more than $200 billion a year in revenue. They also control over 80% of the PBM market, covering 180 million insured people.

7. Critical actors in the drug distribution and pricing system, PBMs serve as middlemen between health insurers and drug manufacturers. In this role, PBMs negotiate medicine prices with drug manufacturers on behalf of insurers. Based in part on the prices they

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[3] Kasia Lipska, *Break Up the Insulin Racket*, NEW YORK TIMES (Feb. 20, 2016), https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket.html.

are able to secure, the PBMs set up tiered formularies for their clients (the health insurers). Formularies are ranked lists of drugs, where cheaper and more effective medicines are generally placed into lower tiers. The health insurers rely on these formularies to determine how much of their members' drug costs they will cover. Drugs in lower, preferred formulary tiers are cheaper for plan members.

8. Where two medicines are largely interchangeable, a PBM will sometimes exclude the more expensive of the two from its formulary. When a drug is excluded from formulary, health insurers using that formulary will not reimburse their members for purchase of that drug. As a result, formularies enable PBMs to push patients toward certain brands of drugs over others, giving them enormous control over drug purchasing behavior.

9. To secure the PBMs' business, drug companies, including Defendants, offer PBMs prices that are lower than their publicly reported, benchmark prices. Both the PBMs and drug companies refuse to disclose these lower, real prices, labeling them trade secrets. The public-facing justification for such secrecy is: "we do not want our competitors to know the extent of our discounts."

10. But there is a second, more nefarious reason for such concealment. As compensation for their role as negotiator, the PBMs pocket a percentage of the difference between the reported benchmark price and the undisclosed real price they secure. This difference is known as the "spread." As the spread between benchmark and real price widens, so too do the PBMs' cut. PBMs do not disclose this spread because they do not want the public to know their profit margins on medications. The Defendant drug companies do not disclose this spread because they do not want the public to realize that their benchmark prices are wildly inflated.

11. Drug manufacturers, including Defendants, can manipulate this dynamic to the detriment of patient consumers. Where two or more drug manufacturers make largely interchangeable products, those companies would, in an ideal world, continuously drop their real prices to undercut the prices offered by their competitors. But the practice of publicly-publishing one price, while secretly offering another, has enabled drug manufacturers competing within the same therapeutic class to secure PBM business without significantly reducing their real prices. The drug companies know that the PBMs stand to profit from large spreads between real and benchmark prices. Inflated benchmark price increases do not cost the PBMs so long as real prices remain constant (after all, they pay the real price, not the benchmark price). Taking advantage of these realities, drug manufacturers competing with the same therapeutic class have begun to offer the PBMs higher *benchmark price*s instead of lower *real* prices. In other words, instead of marketing lower *real* prices to PBMs, they market the spread *between* prices. The drug manufacturer with the largest spread between benchmark and real price is more likely to secure a PBM's preferred formulary position, and, as a result, the business of that PBM's clients.

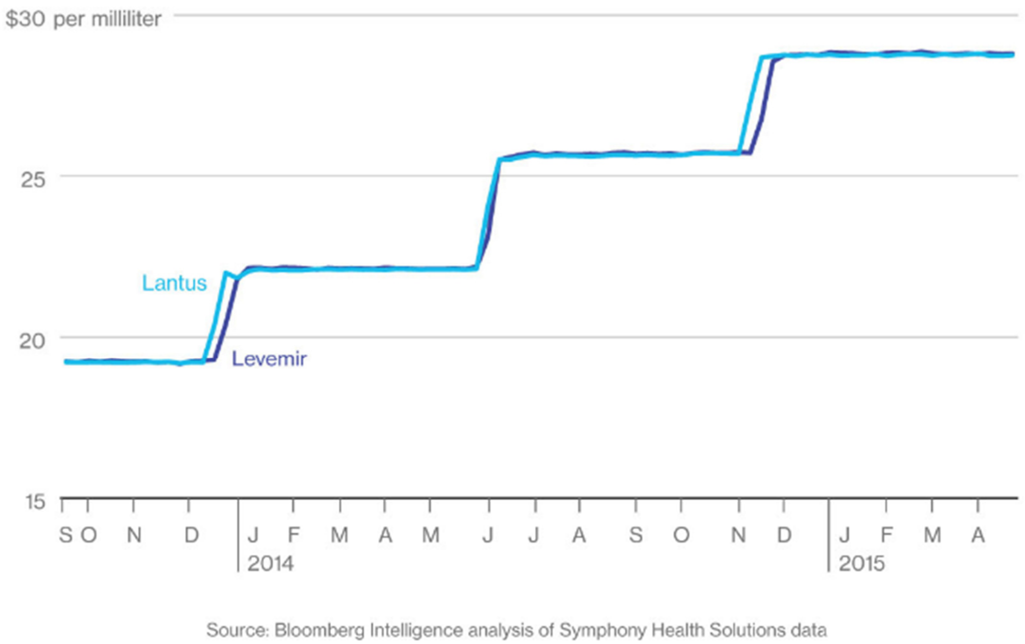
12. This is exactly what has occurred in the market for analog insulin treatments. Defendants Sanofi, Novo Nordisk, and Eli Lilly have offered the three largest PBMs—CVS Health, Express Scripts, and OptumRx—larger spreads as *quid pro quo* for patient business.

13. There are two types of analog insulin: long-acting and rapid-acting. Sanofi and Novo Nordisk both make long-acting analog insulin—Lantus and Levemir, respectively. These drugs are direct competitors in the long-acting insulin category. Novo Nordisk and Eli Lilly compete in the rapid-acting category, manufacturing Novolog and Humalog, respectively.

14. All three Defendants have exponentially raised the benchmark prices of their medicines while maintaining constant (and even slightly lowering) their real prices. This

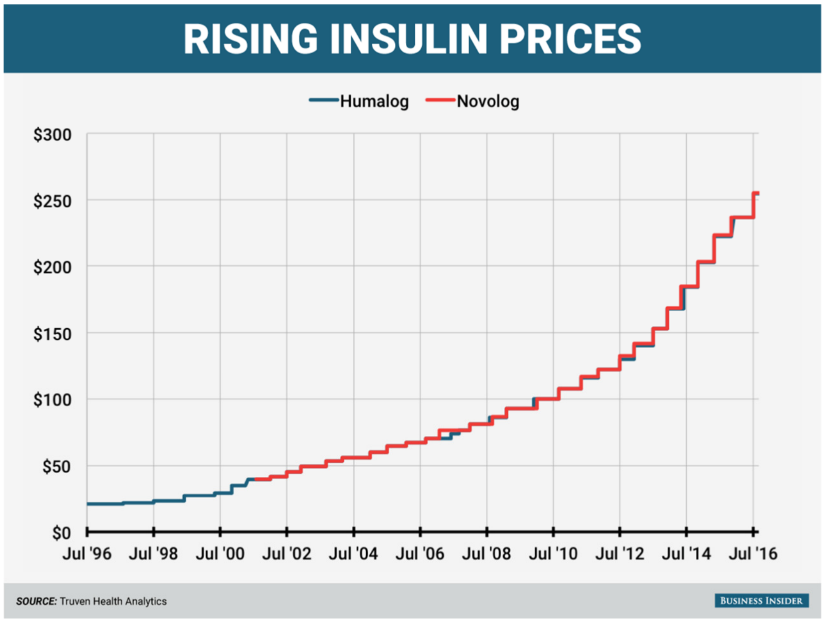
behavior has enabled them to market larger spreads to the big PBMs in exchange for formulary status. Insidiously, an arms race in the escalation of reported benchmark prices—and consequently spreads—has ensued between Defendants: each Defendant raises its benchmark price just a bit more than its competitors, encouraging the large PBMs to keep its drug on formulary. And Defendants have done so in perfect lock step:

Figure 1: Sanofi and Novo Nordisk Increase Long-Acting Insulin Benchmark Prices in Lock-Step[4]


$30 per milliliter
25
20
15
Lantus
Levemir
S O N D J F M A M J J A S O N D J F M A
2014
2015
Source: Bloomberg Intelligence analysis of Symphony Health Solutions data

[4] Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2016), http://www.bloomberg.com/news/articles/2015-05-06/diabetes-drugs-compete-with-prices-that-rise-in-lockstep.

Figure 2: Eli Lilly and Novo Nordisk Increase Rapid-Acting Insulin Benchmark Prices in Lock-Step[5]


RISING INSULIN PRICES
Humalog
Novolog
$300
$250
$200
$150
$100
$50
$0
Jul '96
Jul '98
Jul '00
Jul '02
Jul '04
Jul '06
Jul '08
Jul '10
Jul '12
Jul '14
Jul '16
SOURCE: Truven Health Analytics
BUSINESS INSIDER

15. Eli Lilly basically admitted to the spread pricing scheme in a statement issued in January 2017 from Eli Lilly spokeswoman Julie Williams:

> There is a wide and growing discrepancy between the published "list price" Lilly sets and the "net price" that Lilly actually receives.
>
> The list price (also known as the wholesale acquisition cost or WAC) is the price that a manufacturer sets as a starting point for negotiations with federal and state governments, private insurers, and pharmacy benefit managers to gain formulary access. Manufacturers also use list price in negotiations with wholesalers and others involved in the distribution process.
>
> The amount the manufacturer receives after all discounts and rebates are applied is considerably less than the list price. For example, the net price for Humalog – our most commonly used insulin – increased by 4 percent over the five-year period of 2009 to 2014, which is a much smaller increase than what some consumers have experienced.

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[5] Lydia Ramsey, *A 93-year-old Drug that Can Cost more than a Mortgage Payment Tells Us Everything that's Wrong with American Healthcare*, Business Insider (Sept. 16, 2016), http://www.businessinsider.com/insulin-prices-increase-2016-9.

16. The NEW YORK TIMES op-ed called for transparency in setting prices:[6]

> In the meantime, we need a fair and transparent system for setting prices. In much of Europe, insulin costs about a sixth of what it does here. That's because the governments play the role of pharmacy benefit managers. They negotiate with the manufacturer directly and have been very effective at driving down prices. In the United States, we rely on the private sector and a free market for drug pricing. But in order for this to work, we need to regulate it better and demand greater transparency.

17. This benchmark price inflation has a victim—patients who rely on insulin to stay alive. Patients' out-of-pocket payments for their medications are typically based on their drugs' reported *benchmark price*s, not their concealed *real* prices. As a result, Defendants' benchmark price arms race has saddled individuals living with diabetes—whether insured and paying benchmark prices before they hit their large deductibles, insured and paying increasingly common coinsurance, or uninsured and paying full benchmark prices for all drugs—with crushing out-of-pocket expenses.

18. The physical, emotional, and financial tolls of paying such excessive prices for insulin are devastating. Unable to afford their insulin drugs, patients report under-dosing their insulin, injecting expired insulin, and starving themselves to control their blood sugars with as little insulin as possible. These behaviors are dangerous for people living with diabetes. Because they ineffectively control those individuals' blood sugar levels, these practices can lead to serious complications such as kidney failure, heart disease, blindness, infection, and amputations. Unable to afford the insulin her doctor prescribes, one patient reports she is currently losing circulation to her foot. She may lose the foot if she does not find a way to obtain the insulin she needs at a lower price. Other class members have intentionally allowed themselves to slip into Diabetic Ketoacidosis—a potentially fatal blood syndrome caused by lack of insulin in the body—so that they can obtain insulin samples from hospital emergency rooms.

[6] Lipska, *supra* n.3.

Multiple Class members explain that they now avoid the doctor because their inability to afford insulin has caused their blood sugars to spike. They know that their doctors will prescribe more insulin to treat this problem, and they simply cannot afford to take any more insulin. Other patients describe how the amount they spend on insulin makes it impossible for them to maintain the healthy diet that people with diabetes need, further compromising their health: "Eating healthy is expensive and if I have to choose between my insulin and eating right, I'll buy my insulin, even if I know it's making my diabetes worse." Thus, while the purpose of insulin is to improve the health of those living with diabetes, the rising and excessive costs of these drugs are actually forcing them to harm their health.

19. The financial strain of these excessive insulin prices infects all areas of patients' lives. Stories of patients taking out loans and accruing debt to afford insulin are common. Multiple patients estimated that they spend over 50% of their monthly income on insulin medications. Some patients have been unable to leave bad jobs for fear of losing their health insurance; others have been encouraged to leave good jobs for positions that might pay more or have better insurance. Many patients describe rearranging their lives around their insulin costs—keeping lights off and the heat low to avoid high electricity bills, moving back in with parents, and even leaving school. One patient's husband joined the U.S. Navy, in part, so that she could get her insulin through the U.S. Navy health plan. As another patient put it, "[f]inancially, it's killing me."

20. The financial difficulties that the price hikes have imposed upon those living with diabetes also have serious mental health consequences. Many patients describe the constant stress and worry that accompanies not knowing how they will pay for next month's insulin supply. "I often cry, and I think, have I done something wrong that I can't afford to take care of

myself?" Another patient explained that she tries not to fill her prescription too often because the cost of her insulin causes her to fight with her husband. Still others express anger and a deep sense of betrayal that a once affordable drug is now completely unaffordable. "I feel so taken advantage of; now, I can't afford my medications, and for what? All so some drug company can profit from my sickness?" In short, a medication that should be a source of health has instead become a cause of pain.

21. This action alleges that the three makers of analog insulin drug products—Sanofi, Novo Nordisk, and Eli Lilly—violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962, and various state consumer protection laws by engaging in a scheme and enterprise whose purpose was unlawfully inflating the benchmark prices of rapid- and long-acting analog insulin drugs and then marketing the spread between the benchmark prices and real prices to PBMs. This scheme directly and foreseeably causes consumers to overpay for these life-saving medications.

22. Further, these lock step price increases are the result of an agreement among defendants not to compete based on price in violation of the Sherman Act 15 U.S.C. §§ 1 and 3.

JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiffs' claims arise under federal law, and under 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962. This Court also has jurisdiction pursuant to 28 U.S.C. § 1332(d), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interests and costs, and is a class action in which any member of a class of Plaintiffs is a citizen of a state different from any Defendant. Finally, this

Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367.

24. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), and 18 U.S.C. § 1965, because each Defendant transacts business in, is found in, and/or has agents in the District of Massachusetts, and because some of the actions giving rise to the complaint took place within this district.

25. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

PARTIES

26. Plaintiffs Hector Valdes and Hector J. Valdes are father and son residents and citizens of Florida. Hector Valdes regularly purchases insulin, and, during the Class Period, paid out-of-pocket for insulin, including Humalog products, at prices that were based on a benchmark price that had been artificially inflated as a result of Defendants' scheme. Hector J. Valdes regularly purchases insulin, and, during the Class Period, paid out-of-pocket for insulin, including Lantus and Novolog products, at prices that were based on a benchmark price that had been artificially inflated as a result of Defendants' scheme. As a result, both Plaintiffs were overcharged and otherwise injured by Defendants during the Class Period.

27. Defendant Sanofi-Aventis U.S., LLC ("Sanofi"), is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi manufactures Lantus and Lantus SoloSTAR (together "Lantus") indicated

for the treatment of diabetes. Since 2013, Sanofi has had over $4 billion in Lantus sales every year. In 2016, Sanofi's Lantus sales revenue was $6.98 billion. Sanofi's SEC Form 20-F for the year 2015 notes that "Lantus is particularly important; it was the Group's leading product . . . representing 17.2% of . . . net sales."

28. Defendant Novo Nordisk Inc. ("Novo Nordisk") is a Delaware corporation and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. Novo Nordisk manufactures Novolog and Levemir, which are indicated for the treatment of diabetes. Novo Nordisk's revenue from the sale of Novolog in 2016 was $3.03 billion, and over $2 billion in 2014 and 2015. Revenues from Levemir were $955 million in 2013, $1.3 billion in 2014, and $1.3 billion in 2015. Sales to diabetic patients is such a critical part of Novo Nordisk's business that the 2015 Annual Report's cover page states in bold letters asks **"Why Do So Many People in Cities Get Diabetes?"**

29. Defendant Eli Lilly and Company ("Eli Lilly") is a corporation organized and existing under the laws of the State of Indiana and has a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly manufactures Humalog, which is indicated for the treatment of diabetes. Lilly's revenue from Humalog in 2016 was $2.84 billion. Lilly's revenues from Humalog were $1.5 billion in 2013 and $1.7 billion in 2015.

30. Various other entities and individuals currently unknown to Plaintiffs may have also participated as co-conspirators in the acts complained of and/or performed acts that aided and abetted and/or otherwise furthered the conspiracy's objectives and unlawful conduct alleged herein.

31. The wrongful acts alleged to have been done by any one Defendant or co-conspirator were authorized, ordered, or done by its directors, officers, managers, agents,

employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

CLASS ALLEGATIONS

32. Plaintiffs bring this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a) and (b)(3), as representatives of a Class defined as follows:

> All persons who or which, from at least as early as January 1, 2013 to the present, paid in the United States or its territories and possessions any portion of the purchase price for a prescription of a Lantus, Levemir, Novolog, and/or Humalog product at a price calculated by reference to a benchmark price, such as AWP (Average Wholesale Price).
>
> Excluded from the Class are: (i) Defendants and their legal representatives, affiliates, directors, officers, assignees, and employees; (ii) any entities in which any Defendant has a controlling interest and their legal representatives, affiliates, directors, officers, assignees, and employees; (iii) any co-conspirators and their legal representatives, affiliates, directors, officers, assignees, and employees; and (iv) any governmental entity.

33. There are a number of ways in which a person may pay a portion of the purchase price of Lantus, Levemir, Novolog, and/or Humalog and thereby gain inclusion in the class. First, a person may be uninsured and, therefore, responsible for paying 100% of the cost of her prescription needs (the "uninsured scenario"). Second, a person's insurance plan may require her to satisfy a deductible before insurance benefits cover all or a portion of their prescription needs. If so, that person is paying for 100% of the cost of any prescriptions filled before the deductible is met (the "deductible scenario"). Third, a person may have a coinsurance requirement—an obligation to a portion of any prescription or medical benefit that they purchase, which is expressed as a percentage of the cost of the medication or service provided (the "coinsurance scenario"). If so, she would be responsible for paying for a portion of the Lantus, Levemir, Novolog, and/or Humalog purchase, consistent with the terms of her plan.

Fourth, a person may obtain insurance through a Medicare Part D Plan; if so, there is a coverage gap, often referred to as the "Donut Hole" (the "Donut Hole scenario"). Once that person and her plan has spent a stated amount of money on prescription drugs, the person becomes responsible for 40% of the cost of her brand-name prescriptions until her total annual out-of-pocket expenses reaches the next stated benchmark amount. After this benchmark, her plan covers the majority of her drug costs again. All of these individuals qualify as direct purchasers.

34. In each of these scenarios—the uninsured scenario, the deductible scenario, the coinsurance scenario, and the Donut Hole scenario—a person's out-of-pocket expenses for Lantus, Levemir, Novolog, and/or Humalog are determined by the benchmark prices of these drugs. Accordingly, each falls within the class definition.

35. Members of the class are so numerous and geographically dispersed that joinder of all members is impracticable. Hundreds of thousands of prescriptions are written for Lantus, Levemir, Novolog, and Humalog throughout the United States every week, and these prescriptions are filled by hundreds of thousands of individuals. The class is readily identifiable from information and records in Sanofi, Novo Nordisk, and Eli Lilly's possession.

36. Plaintiffs' claims are typical of the claims of the members of the class. Plaintiffs and all members of the class were damaged by the same wrongful conduct of Defendants—*i.e.*, as a result of Sanofi, Novo Nordisk, and Eli Lilly's misconduct, these purchasers paid artificially-inflated prices for Lantus, Levemir, Novolog, and/or Humalog.

37. Plaintiffs will fairly and adequately protect and represent the interests of the class. The interests of Plaintiffs are coincident with, and not antagonistic to, those of the other members of the class.

38. Counsel that represent Plaintiffs are experienced in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products and extensive experience in class actions including the use of benchmark pricing, including two cases in the district (AWP and McKesson) that resulted in recovery in excess of $500 million.

39. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members because Defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

40. Questions of law and fact common to the class include:

i. Whether the benchmark price set by Sanofi, Novo Nordisk, or Eli Lilly is used as a benchmark for payments by class members;

ii. What the benchmark price for Lantus, Levemir, Novolog, and Humalog is;

iii. Whether Sanofi, Novo Nordisk, and Eli Lilly are engaged in a course of conduct that improperly inflated the benchmark-to-real price ratio and the ultimate benchmark price used by Plaintiffs and class members as a basis for reimbursement;

iv. Whether Defendants artificially inflated the benchmark price;

v. Whether Defendants gave rebates to PBMs that created substantial spreads between the benchmark price and PBM negotiated price;

vi. Whether the large spread between these prices benefitted the PBMs;

vii. Whether the large benchmark-to-real price spread was intended to induce the PBMs to give Lantus, Levemir, Novolog, and/or Humalog favorable placement on the PBMs' formularies;

viii. Whether the large spread did induce the PBMs to give Defendants favorable placement on the PBMs' formularies;

ix. Whether each Defendant conspired with the PBMs from the Pricing Enterprise for the purpose of carrying out its pricing fraud;

x. Whether Defendants conducted, or participated in the conduct of, the Pricing Enterprise;

xi. Whether Defendants or the PBMs engaged in mail or wire fraud in furtherance of the Pricing Enterprise;

xii. Whether Defendants engaged in a pattern and practice that caused Plaintiffs and class members to make inflated payments for Lantus, Levemir, Novolog, and/or Humalog;

xiii. Whether Defendants engaged in deceptive fraudulent conduct;

xiv. Whether Defendants' deceptive and/or fraudulent activity was intended to defraud or harm Plaintiffs and class members;

xv. Whether Defendants' conduct violated RICO or the State Consumer Protection Statute; and

xvi. Whether Defendants are liable to Plaintiffs and the class members for damages flowing from their misconduct.

41. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

42. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

FACTUAL ALLEGATIONS

I. DRUG PRICING IN THE UNITED STATES

A. The Entities Involved in Drug Pricing

43. The prescription drug industry consists of an opaque and complex network of entities engaged in multiple distribution and payment structures. These entities include

pharmaceutical companies, wholesalers, pharmacies, health insurers, pharmacy benefit managers, and patient-consumers.

44. ***Pharmaceutical Companies***. Pharmaceutical companies (also known as drug companies or drug manufacturers) own the rights to manufacture and market drugs. This remains true even if these companies contract out the actual production of their drugs. Pharmaceutical companies typically own or contract with facilities that manufacture drugs and then sell their products to wholesalers.[7] Defendants here are pharmaceutical companies.

45. ***Wholesalers***. After production, many manufacturers send their drugs to FDA-registered drug wholesalers for further distribution.[8] Wholesalers purchase, inventory, and sell pharmaceutical products to a variety of providers, including retail pharmacy outlets, hospitals, and clinics.[9] States license or authorize wholesalers that sell and distribute pharmaceuticals within their borders.[10] The wholesaler market in the United States is dominated by three companies: AmerisourceBergen Corp., Cardinal Health, Inc., and McKesson Corp.[11]

46. ***Health Insurers***. Health insurers submit payments on behalf of insured individuals to health care providers for services rendered to the insured individuals.[12] Health

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[7] *See, e.g.*, Ernst Berndt & Joseph Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets* (Harvard Kennedy School, National Bureau of Economic Research, Sept. 2010), at 8.
[8] *Id.*
[9] *See Guidance for Industry: Prescription Drug Marketing Act (PDMA) Requirements*, Food and Drug Admin. (Nov. 2006), at 3, *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm134399.pdf.
[10] *See Profile of the Prescription Drug Wholesaling Industry*, Food and Drug Admin., 3, *available at* http://www.fda.gov/ohrms/dockets/dockets/05n0403/05n-0403-bkg0001-04-02-1.pdf.
[11] *See* Susan Thaul, *Pharmaceutical Supply Chain Security*, Cong. Research Serv., R43106, 4 (Oct. 31, 2013).
[12] *See* Thomas Bodenheimer, *High and Rising Health Care Costs. Part 1: Seeking an Explanation*, 142 Ann. Internal Med. 847, 847 (May 17, 2005).

insurers also cover a portion of their members' drugs costs, submitting payments to pharmacies on behalf of their members. The term "health insurers" covers self-insured businesses, insurance companies, including those that participate in Medicaid and Medicare, and union-run health plans.[13]

47. ***Pharmacy Benefit Managers***. As previously explained, pharmacy benefit managers ("PBMs") act as intermediaries between drug manufacturers and health insurers.[14] In this role, PBMs perform a variety of services on behalf of their health care payer clients, including the negotiation of drug prices with drug companies, creation of formularies, management of prescription billing, construction of retail pharmacy networks for insurers, and provision of mail-order services.[15] Nonetheless, they generally are "not a direct link in the physical supply chain for pharmaceutical products" because, in most instances, they do not take possession or control of prescription drugs.[16] The largest PBMs are Express Scripts Holdings Co., CVS Health Corp., and UnitedHealth Group's OptumRx.[17] Some of these PBMs, such as CVS Health, are part of corporations that also own their own retail pharmacies.

B. The Drug Payment and Distribution Structure

48. While payment varies from drug to drug, the basic payment structure follows this rubric: The patient pays her health insurer (via her health insurance premium), which pays the pharmacy, which pays the wholesaler and PBMs, which pays the pharmaceutical company. Similarly, while distribution systems vary across drugs, the common structure involves the drug

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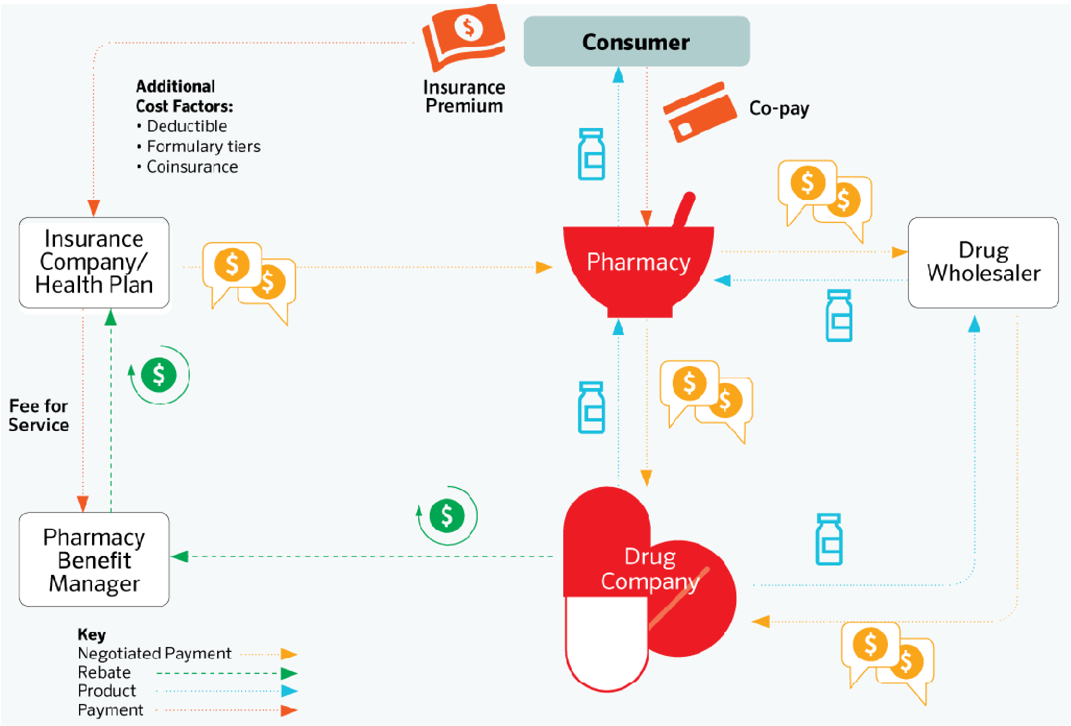
[13] *Id.*
[14] *See* Thomas Gryta, *What is a 'Pharmacy Benefit Manger'*, WALL STREET JOURNAL (July 21, 2016), http://www.wsj.com/articles/SB10001424053111903554904576460322664055328.
[15] *Id.*
[16] *See* The Health Strategies Consultancy LLC, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, The Kaiser Family Foundation, 14 (Mar. 2005), http://avalere.com/research/docs/Follow_the_Pill.pdf.
[17] *See Pharmacy-Benefit Managers*, THE WALL STREET JOURNAL (Mar. 30, 2015), http://blogs.wsj.com/briefly/2015/03/30/pharmacy-benefit-managers-the-short-answer/.

manufacturer distributing to the pharmacies and wholesalers, who then distribute to the patient-consumers.

49. The figure below illustrates this highly complex payment structure.[18] This figure labels certain payments "payment" and others "negotiated payment." The term "payment" refers to individual payments, made at the time of delivery. For example, when a patient walks into a pharmacy and picks up her prescription. At that moment, her health plan also pays a service fee to its PBM for dispensing the drug through its network of retail pharmacies. In contrast, "negotiated payment" is a payment made under a negotiated contract. For example, a PBM might negotiate a contract with a drug manufacturer for supply of X drug for $Y per pill for two years. The figure also indicates the flow of products and rebates.

Figure 3: The U.S. Drug Payment Structure[19]


Consumer
Insurance Premium
Co-pay
Additional Cost Factors:
• Deductible
• Formulary tiers
• Coinsurance
Insurance Company/ Health Plan
Pharmacy
Drug Wholesaler
Fee for Service
Pharmacy Benefit Manager
Drug Company
Key
Negotiated Payment
Rebate
Product
Payment

[18] U.S. Gov't Accountability Office, *Generic Drugs Under Medicare*, GAO-16-706, at 7 (Aug. 2016).
[19] Allison Tsai, *The Rising Cost of Insulin*, Diabetes Forecast (Mar. 2016), http://www.diabetesforecast.org/2016/mar-apr/rising-costs-insulin.html.

50. When an insured consumer buys a medication from a pharmacy, her insurer pays the pharmacy based on the price its PBM negotiated. In addition to her insurer's payment, the patient usually pays her pharmacy a portion of her medication's cost, out-of-pocket.

51. Insurers get their cash flow from consumers, who purchase insurance coverage. Consumers typically pay their insurers fixed monthly premiums for their health insurance plans. The health insurer relies on these monthly premiums to pay for the prescription drug needs of its members.

52. Pharmacies usually obtain the drugs they distribute from wholesalers or the manufacturers. The wholesalers purchase these drugs directly from the pharmaceutical manufacturers.[20]

C. Different Prices for Different Players

53. The prices for the drugs distributed in this chain are different for each participating entity. In other words, different actors pay different prices for the same drugs. In this system, only a drug's benchmark price—also known as its Average Wholesale Price ("AWP")—is publically reported.

54. This price serves as the starting point for negotiations between PBMs and drug manufacturers. PBMs use their formulary control to exact steep discounts from drug companies, known as "rebates." As previously explained, PBMs create formularies for their health insurer clients and those formularies significantly influence patients' drug purchasing behavior. Health insurers cover all or a portion of their members' drug costs based on whether and where drugs fall on the PBMs' formularies. Sometimes, a drug company will offer one large PBM a deeper price discount than it offers other PBMs in exchange for an exclusive formulary position. The

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[20] *See* U.S. Dep't of Health & Human Servs., The Assistant Sec'y for Planning and Evaluation, *Prescription Drug Prices*, 100 (Apr. 1, 2000), https://aspe.hhs.govisites/defaultfiles/pdfi1721711c3.pdf.

PBM's health insurer clients, who adhere to the PBM's formulary, will then only reimburse their plan members for purchase of the drug with the exclusive position. As a result, PBMs have significant control over what drugs consumers purchase.[21] They are able to leverage this power to procure deep price discounts.

55. PBMs pass on an undisclosed portion of the discounts or "rebates" they receive to their health insurer clients. Therefore, insurers also pay much lower prices than the benchmark prices.

56. Wholesalers are also able to use their bulk purchasing power to negotiate lower drug prices from the drug companies.

57. In the end, the only actors who actually pay the full drug benchmark prices are consumers who are uninsured or insured but paying for drugs out-of-pocket before they hit their deductibles. Rising benchmark prices also harm patients who pay coinsurance or reach the Medicare Part D "Donut Hole," because these consumers' payments are tied to the drugs' benchmarks prices. As benchmark prices rise, so too do consumer payments.

D. Consumer Drug Costs

58. ***Uninsured***. Uninsured consumers must pay the full benchmark price every time they pick up their prescriptions. Despite the Affordable Care Act's expansion of Medicaid coverage and establishment of Health Insurance Marketplaces, millions of people—28.5 million in 2015—remain without coverage. This uninsured population is especially concentrated in states that did not take the Medicaid expansion, where diabetes is prevalent. Of the 28.5 million uninsured, reports indicate that 46% tried to get coverage but could not afford it. The uninsured

[21] *See* Robert F. Atlas, *The Role of PBMs in Implementing the Medicare Prescription Drug Benefit*, 23 Health Affairs w4-504, w4-507 (July 2004).

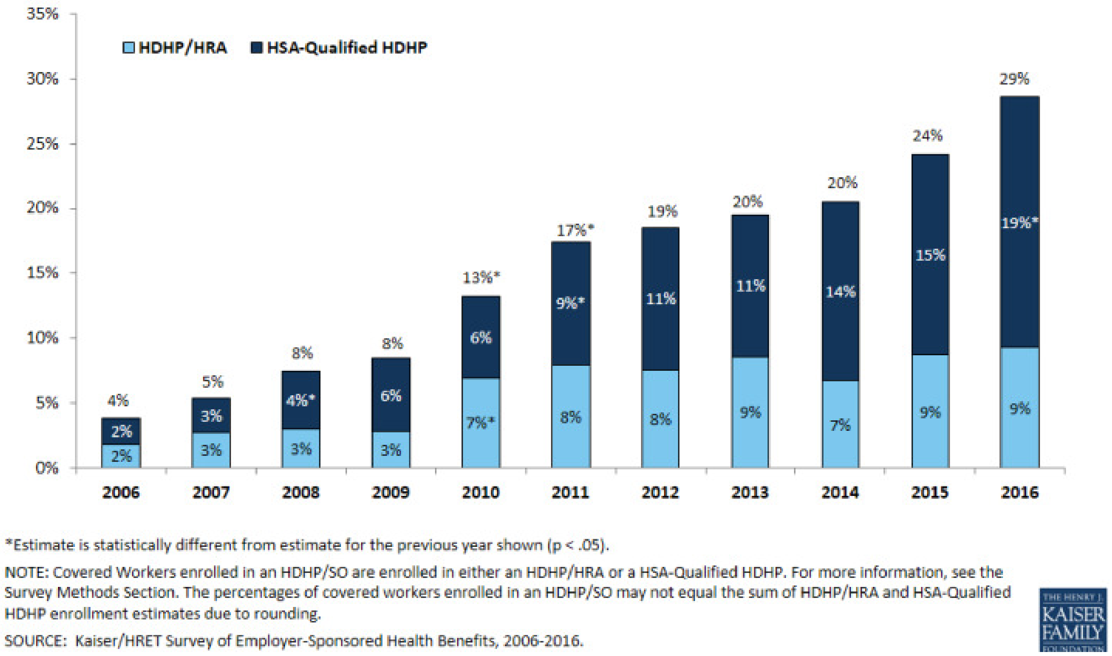
population may grow drastically in the next few years if the Affordable Care Act is repealed without a suitable replacement.

59. But the uninsured are not the only patients saddled with high out-pocket-costs. Despite their monthly insurance premiums, insured consumers often still pay all or a part of drug benchmark prices. Out-pocket-costs for insured consumers come in three forms: deductibles, coinsurance requirements, and/or copayment requirements.

60. ***High Deductible Plans***. The term "deductible" refers to a set amount of healthcare cost an insured must pay for by herself (out-of-pocket) before her plan will begin to contribute to her healthcare costs. Once a patient reaches her deductible, her health plan begins to contribute, paying a portion of her healthcare costs. Although most health plans have some form of a deductible, high-deductible health plans are aptly named for their larger-than-average deductibles. And while high-deductible health plans usually boast lower premiums, they are nonetheless more onerous to patients and families that need expensive care on a regular basis. Insured individuals in high-deductible plans must usually pay full benchmark prices until they hit their deductibles.

61. The past decade has witnessed a shift away from traditional health plans, which provide broader coverage, toward high-deductible health plans. In their 2016 survey of employer health benefits, the Kaiser Family Foundation found that 29% of all covered employees are now enrolled in high-deductible health plans, up from 17% in 2011. Although Preferred Provider Organizations ("PPOs") are still the most common plan type (48% of Americans are enrolled in PPOs), enrollment in PPOs has fallen 10% over the last two years, while enrollment in high-deductible health plans has increased by 8%. Figure 4 illustrates the rising trend in high deductible plans.

Figure 4: Percentage of Covered Workers Enrolled in High-Deductible Health Plans from 2006-2016[22]


HDHP/HRA
HSA-Qualified HDHP
35%
30%
25%
20%
15%
10%
5%
0%
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
4%
2%
2%
5%
3%
3%
8%
4%*
3%
8%
6%
3%
13%*
6%
7%*
17%*
9%*
8%
19%
11%
8%
20%
11%
9%
20%
14%
7%
24%
15%
9%
29%
19%*
9%
*Estimate is statistically different from estimate for the previous year shown (p < .05).
NOTE: Covered Workers enrolled in an HDHP/SO are enrolled in either an HDHP/HRA or a HSA-Qualified HDHP. For more information, see the Survey Methods Section. The percentages of covered workers enrolled in an HDHP/SO may not equal the sum of HDHP/HRA and HSA-Qualified HDHP enrollment estimates due to rounding.
SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

62. Moreover, deductibles themselves have risen. The average annual deductible for an individual enrolled in a high-deductible plan is now between $2,031 and $2,295, depending on the exact type of plan.[23] The average annual deductible for family coverage is now between $4,321 and $4,364, again, depending on the type of plan.

63. Overall, in the entire employer-based health plan market, deductibles have risen 12% since 2015—four times faster than premiums increased in the same period. Among all individuals enrolled in employer health plans (both high-deductible plans as well as others), the average deductible in 2016 was $1,478.

64. The average deductible for individuals working at smaller firms is higher than that in large firms ($2,069 vs. $1,238).

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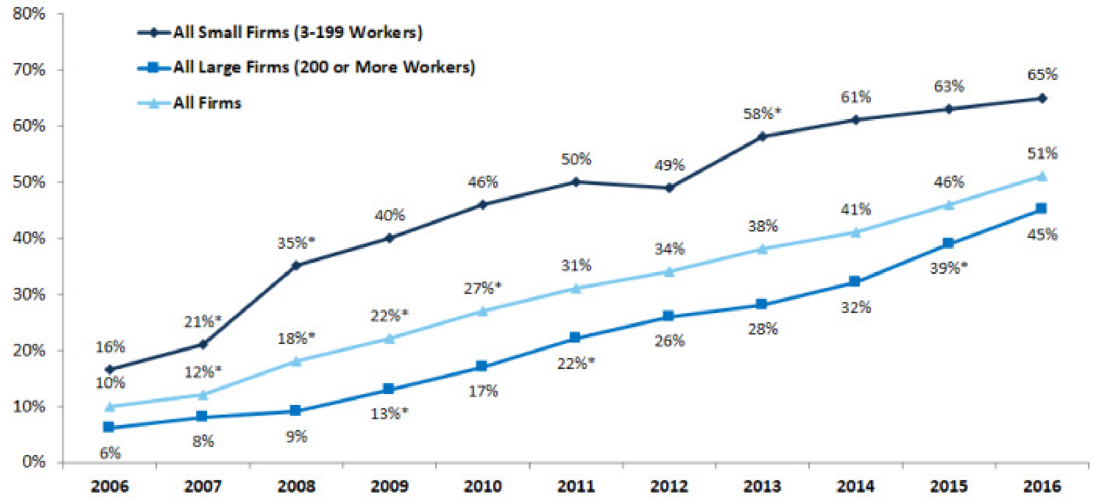
[22] *2016 Employer Health Benefits Survey*, Kaiser Family Foundation, 3 (2016), https://kaiserfamilyfoundation.files.wordpress.com/2016/09/employer-health-benefits-2016-summary-of-findings.pdf.

[23] There are two primary types of high-deductible health plans: high-deductible plans with Health Reimbursement Arrangements and high-deductible plans with Health Savings Accounts.

65. Figure 5 shows the increase in health plans with a general annual deductible of $1,000 or more, broken down by firm size.

Figure 5: Percentage of Covered Workers Enrolled in a Plan with a General Annual Deductible of $1000 or More for Single Coverage, by Firm Size, from 2006-2016[24]


80%
70%
60%
50%
40%
30%
20%
10%
0%
All Small Firms (3-199 Workers)
All Large Firms (200 or More Workers)
All Firms
16%
21%*
35%*
40%
46%
50%
49%
58%*
61%
63%
65%
10%
12%*
18%*
22%*
27%*
31%
34%
38%
41%
46%
51%
6%
8%
9%
13%*
17%
22%*
26%
28%
32%
39%*
45%
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016

* Estimate is statistically different from estimate for the previous year shown (p < .05).

NOTE: These estimates include workers enrolled in HDHP/SO and other plan types. Average general annual health plan deductibles for PPOs, POS plans, and HDHP/SOs are for in-network services.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

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66. The average deductibles for plans available under the Affordable Care Act on the Marketplace Exchanges are also high. The Marketplace health plans are broken into "metal" tiers: bronze, silver, gold, and platinum. The cheapest plans—bronze and silver—unsurprisingly come with very high deductibles. In 2016, the average deductible in such plans were $5,765 for bronze plans (up from $5,328 in 2015) and $3,064 for silver plans (up from $2,556 in 2015).

67. Many individuals and families cannot afford to hit their high-deductible costs year after year. As a result, rising drug benchmark prices are particularly harmful to patients in high-deductible plans.

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[24] *2016 Employer Health Benefits Survey*, Kaiser Family Foundation, 4 (2016), https://kaiserfamilyfoundation.files.wordpress.com/2016/09/employer-health-benefits-2016-summary-of-findings.pdf.

68. **Coinsurance and Copayments**. In addition to their deductibles, individuals with insurance must usually make copayments or coinsurance payments for the healthcare services they need. A copayment is a fixed fee that an individual must pay for a healthcare service at the time of care. For drugs, copayments are fixed fees that consumers pay when they pick up their prescriptions. Copayment rates vary depending on the drug; drugs in preferred formulary positions have lower copays, and drugs in disfavored formulary positions require larger copays.

69. **Coinsurance is similar**. However, instead of paying a fixed fee for a particular service, individuals with coinsurance arrangements must pay a fixed percentage of the cost of the healthcare service provided. For drugs, this means a percentage of the drug's benchmark price. This percentage varies depending on the drug, with lower coinsurance rates for preferred drugs, and higher coinsurance rates for disfavored drugs.

70. For those who must pay full benchmark prices until they hit their deductibles, copayments and coinsurance obligations begin after they reach their deductibles. Plans that cover prescription drugs right away, not requiring patients to reach their deductibles first, require copayments or coinsurance contributions for every drug purchase.

71. For covered workers enrolled in health plans with three or more tiers of cost sharing for prescription drugs, average coinsurance rates are 17% for first-tier drugs, 25% for second-tier drugs, 37% for third-tier drugs, and 29% for fourth-tier drugs. Lantus, Levemir, Humalog, and Novolog are still branded drugs. Therefore, insurance plans generally classify them as second or third-tier drugs on their formularies. As a result, coinsurance payments for these drugs can be quite burdensome.

72. Recently, health plans have been demanding higher and higher coinsurance contributions from patients. Table 1 shows this trend.

Table 1: Rising Coinsurance Rates

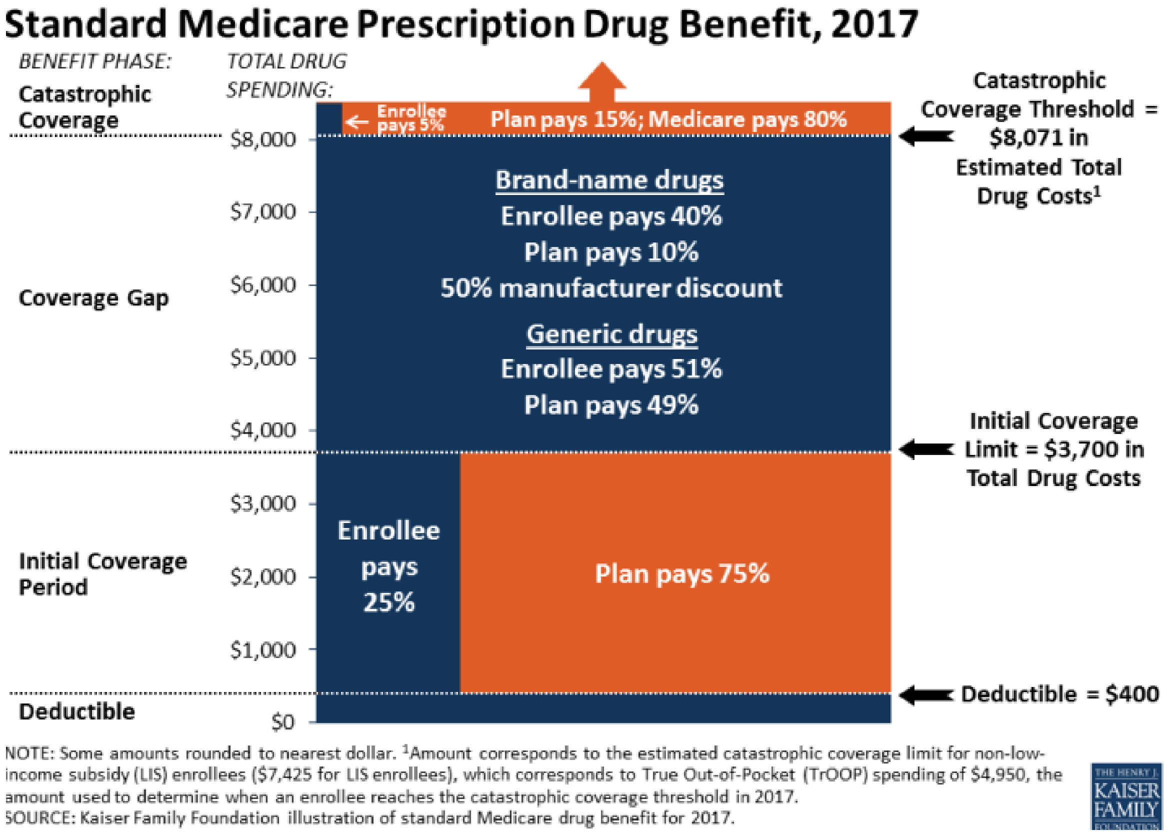
Retail Coinsurance Payment			
	T2 Brand	T3 Brand	Flat
1998	24.7%	26.0%	20.7%
1999	24.9%	26.9%	21.0%
2000	26.0%	28.0%	22.0%
2001	24.0%	29.0%	20.0%
2002	24.4%	34.7%	23.0%
2003	24.3%	32.4%	22.0%
2004	25.0%	32.0%	25.0%
2005	26.5%	35.6%	23.0%
2006	26.2%	36.0%	23.0%
2007	26.4%	37.9%	22.0%
2008	26.1%	37.0%	24.0%
2009	26.3%	35.8%	22.0%
2010	25.2%	36.6%	24.0%
2011	25.6%	37.9%	23.0%
2012	26.1%	37.6%	22.0%
2013	25.5%	37.1%	22.0%
2014	24.3%	35.9%	22.0%
2015	27.1%	41.8%	22.0%

73. Overall, out-of-pocket spending for prescription drugs has shifted away from copayments, toward deductible and coinsurance spending over the past decade. In 2014, patients paid for 24% of their out-of-pocket prescription drug expenses through deductibles, compared to just 4% in 2004. Similarly, patients paid for 20% of their out-of-pocket drug expenses through coinsurance in 2014, compared to just 3% in 2004.

74. **Medicare Part D**. Finally, patients in Medicare Part D plans—Medicare's prescription drug program—often pay a large portion of their drugs' benchmark prices. In 2017, the Medicare Part D standard prescription drug plan will have a $400 deductible and a 25% coinsurance obligation up to an initial coverage limit of $3,700. Once Medicare Part D patients meet this $3,700 limit, they fall into the coverage gap, more commonly known as the "Donut Hole." In the Donut Hole, patients must pay 40% of their brand-name drugs' benchmark prices.

Only once patients total out-of-pocket spending reaches $4,950 will Medicare begin to shoulder 80% of their healthcare costs again. Figure 6 demonstrates patient cost-sharing in the standard Medicare Part D plan for 2017.

Figure 6: Standard Medicare Prescription Drug Benefit, 2017[25]


Standard Medicare Prescription Drug Benefit, 2017
BENEFIT PHASE:
TOTAL DRUG SPENDING:
Catastrophic Coverage
Enrollee pays 5%
Plan pays 15%; Medicare pays 80%
$8,000
$7,000
$6,000
$5,000
$4,000
$3,000
$2,000
$1,000
$0
Brand-name drugs
Enrollee pays 40%
Plan pays 10%
50% manufacturer discount
Generic drugs
Enrollee pays 51%
Plan pays 49%
Coverage Gap
Catastrophic Coverage Threshold = $8,071 in Estimated Total Drug Costs¹
Initial Coverage Limit = $3,700 in Total Drug Costs
Initial Coverage Period
Enrollee pays 25%
Plan pays 75%
Deductible
Deductible = $400
NOTE: Some amounts rounded to nearest dollar. ¹Amount corresponds to the estimated catastrophic coverage limit for non-low-income subsidy (LIS) enrollees ($7,425 for LIS enrollees), which corresponds to True Out-of-Pocket (TrOOP) spending of $4,950, the amount used to determine when an enrollee reaches the catastrophic coverage threshold in 2017.
SOURCE: Kaiser Family Foundation illustration of standard Medicare drug benefit for 2017.
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75. This complex price system leads to patient consumers paying drastically higher prices for insulin than their insurers (if they have insurance). If a patient is responsible for all of her drugs costs before she hits her deductible, she must pay the *benchmark price* until she meets her deductible; if she pays coinsurance, she pays for a percentage of the drug's *benchmark price*; if she is in a Medicare Part D plan and reaches the Donut Hole, she must pay 40% of her brand-name drugs' benchmark prices. In contrast, insurers receive discounts off the drug

[25] *The Medicare Part D Prescription Drug Benefit,* The Kaiser Family Foundation, 6 (Sept. 26, 2016), http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/.

companies' benchmark prices, through their PBMs.[26] In other words, an insurer's payment to the pharmacy at the point of purchase is based on a lower price than the patient's payment.

76. An example helps illustrate this structure. A woman with diabetes needs to purchase a box of insulin pens. She goes to her local retail pharmacy where the pharmacist tells her the box's benchmark price is $450. She has health insurance through her employer, and her insurance plan requires her to pay a $2,000 deductible and then 30% coinsurance after she has hit her deductible. If she has not yet reached her deductible, she pays $450 for the box of insulin. If she has reached her deductible (already paid $2,000 in health care costs), she pays $135 to the pharmacy ($450 x .3) for the box. Her insurance covers the rest of the box's cost. If she assumes that her insurer is paying the remaining $315, she is wrong. The price of this insulin box to her insurer is likely much lower because her insurer has a contract with a PBM and that PBM has negotiated a rebate on the box from the drug company. Although the benchmark price (the one the consumer sees) is $450, the rebated price to the PBM, and therefore the insurer, is much lower.

E. Manipulation of Cost-Saving Incentives: Drug Benchmark Price Competition and the Secret Rebates to PBMs

77. PBMs turn a profit in two primary ways: First, their health insurer clients pay them service fees for processing prescriptions and operating mail-order pharmacies. Second, PBMs take a cut of the drug rebates they negotiate with drug companies (with the rest passed onto their health insurer clients). This rebate arrangement is meant to create an incentive for PBMs to negotiate lower *real* drug prices: the lower the real price they negotiate, the larger the

[26] *See* Congressional Budget Office, *Prescription Drug Pricing in the Private Sector*, 12 (Jan. 1, 2007).

spread (*i.e.*, rebates), the higher their profits.[27] This business model should create incentives for PBMs to control drug costs.

78. PBMs have the greatest leverage to negotiate lower prices when two or more drug companies make interchangeable products—*i.e.*, drugs within the same therapeutic class. In such a scenario, the drug companies should compete on price, as in normal competitive markets, for the PBMs' business.

79. Unfortunately, drug companies and PBMs have found a way to game this system. As both the drug companies and PBMs have realized, the spread can also be enlarged by *raising benchmark prices* while holding *real prices constant*. In exchange for this spread enlargement, the PBMs agree, either explicitly or implicitly, to favor, or at least not disfavor, the drug with the elevated benchmark price. The drug company knows that when a drug has a large benchmark price increase, the PBM will be making substantially greater revenue yet will be paying no more than it previously did so long as the real price does not increase.

80. Of course, manufacturers can (and do) calculate for internal purposes the net sales price at which they are able to sell their products, and the average of those net sales prices is sometimes called the average sales price (ASP) or net selling price. While net acquisition prices and associated ASPs are known to each drug manufacturer, they are not typically published or made public.[28] Some drug manufacturers may have a variety of terms for specific discounts that are based on class of trade, volume of purchase, market share movement, preferred formulary status, terms of payment, and other criteria. Because net price is meant to be the net

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[27] *Id.*

[28] The important exception to this is Congress' recent enactment of the Medicare Modernization Act of 2003, in which Congress changed the Medicare reimbursement system for drugs and biologicals from an AWP-based system to an ASP-based system physician-administered. This exception is not relevant here.

price after all forms of discounts, rebates, purchasing allowances or any other forms of economic consideration have been taken into account, discounts that contribute to the net prices, and the net prices to various PBMs, are considered proprietary and confidential by drug manufacturers.

81. The perverse, reverse incentives for larger benchmark prices (and consequent overpayments by consumers) was described recently in a recent report on the drug industry:

> At the whole-market level, we sense that the price protection rebate arbitrage game is driving manufacturers to higher benchmark price increases than would otherwise occur, particularly on the eve of a general election. Price protection rebates between brand manufacturers and PBMs are common, as are fixed rebate agreements between PBMs and a significant portion of their plan sponsors. When brand manufacturers' [benchmark price] increases exceed the price protection threshold, the manufacturers rebate the difference to PBMs, who pocket the difference when these price protection rebates grow faster than the PBMs' fixed rebate commitments to plan sponsors. Thus all else equal in a given category, the product with the more rapid benchmark price increases is more profitable to the PBM. Manufacturers, realizing this, don't want their products disadvantaged, and accordingly are driven to keep their rates of benchmark price inflation at least as high, and ideally just a bit higher, than peers'. Durable benchmark price inflation is the natural result. Net price inflation is unaffected, but unit volumes suffer as higher benchmark prices directly impact consumers who have not yet met their deductibles. [29]

82. This is not the first instance where PBMs have been caught secretly making money on an increase in the spread between benchmark and real prices. In *New England Carpenters Health Benefits Fund v. First DataBank, Inc.*, 244 F.R.P. 79 (D. Mass. 2007), the court certified a class alleging that McKesson, a wholesaler, and First Data, a drug price publisher, engaged in a scheme to inflate the benchmark prices of brand name drugs. McKesson asserted that a class could not be certified because PBMs had become aware of the phony increase in the spread, and promptly acted to offset the spread by vigorously seeking rebates for its health insurer clients. However, part of the evidence Judge Saris relied upon in rejecting this

[29] Richard Evans, Scott Hinds, & Ryan Baum, *US Rx Net Pricing Trends Thru 2Q16*, SSR LLC, 36 (Oct. 5, 2016).

contention was evidence showing that the PBMs pocketed a portion of the increase in the spread at the expense of consumers and health insurers:

> Because these PBMs benefited from the increased [benchmark price] spreads perpetuated by the Scheme, Plaintiffs argue that they had no incentive to inform [third party payers (*i.e.* health insurers)] of the inflated AWP, let alone fiercely compete to mitigate any damage. As proof, Plaintiffs quote an April 26, 2002 internal ESI e-mail, sent around the same time as the ESI letter, that states that "the AWP increases being pushed through by First Data Bank [are] having a very favorable impact on our mail margins." The e-mail goes on to state, "Our clients will not be sympathetic to our financial situation since we [will have benefited] from the AWP increase in the mail and they hired us to control drug trend." The e-mail includes a handwritten note, in response, "Let's put a lid on it and not make it a big deal."[30]

83. As noted above, the PBMs can use the phony benchmark prices to their advantage. As a result of this scheme, the PBMs gain the opportunity to exact larger rebate profits, without paying any more money for the drugs themselves. And all the while, the PBMs can boast of the "increased rebates" they have achieved, when, in reality, the "discount" they have achieved is simply a reduction off an artificially inflated benchmark price. The drug maker benefits from this scheme by maintaining a formulary position it otherwise may have lost.

84. The losers in this scheme are patients. When drug companies inflate benchmark prices so that they can offer PBMs larger spreads, they harm uninsured patients, who must pay benchmark prices out-of-pocket. They also hurt insured consumers in high-deductible plans who must pay the artificially inflated benchmark prices until they hit their deductibles. Consumers paying coinsurance suffer because their coinsurance payments rise with benchmark price increases. So too do Medicare Part D patients, especially when they reach the Donut Hole.

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[30] *New England Carpenters Health Benefits Fund v. First Data Bank, Inc.*, 248 F.R.D. 363, 367 (D. Mass 2008) (internal citations omitted).

II. LONG-ACTING INSULIN ANALOGS

A. Diabetes: The Disease and Demographics

85. The number of Americans who live with diabetes has exploded in the last half century. In 1958, only 1.6 million people in the United States had diabetes. By the turn of the century, that number had grown to over 10 million. Just 14 years later, the head count tripled again. Now over 29 million people—9.3% of the country—live with the disease. And this trend does not appear to be slowing: 86 million Americans have prediabetes, a health condition that significantly increases a person's risk of type 2 diabetes.

86. Diabetes occurs when a person has too much glucose—sugar—in their blood stream. Normally, the human body breaks down ingested food into glucose, which in turn feeds cells and enables them to function. In this process, insulin functions as a key, opening the cells and permitting glucose to enter. A lack of insulin or responsiveness to insulin causes the process to break down. Glucose is unable to enter the cells, which leads to high blood sugar levels. Unchecked, high blood sugar levels in a non-diabetic can lead to type 2 diabetes.

87. There are two basic types of diabetes. Ninety to 95% of Americans living with diabetes developed the disease because they do not produce enough insulin or have become resistant to the insulin their bodies do produce. Known as type 2, this more common form of diabetes is typically associated with increased body weight and is often developed later in life. In contrast, type 1 diabetes occurs when a patient completely ceases insulin production. This form of diabetes is usually diagnosed in children and young adults, but can occur at any age. A person with type 1 diabetes does not produce any insulin and, without regular injections of insulin, they will die.

88. When first diagnosed, many type 2 patients can initially be treated with tablets that help their bodies either secrete more insulin or better respond to the insulin they already

produce. Nonetheless, these tablets are often insufficient for patients in the long term. To adequately control their blood sugar levels, many type 2 patients must inject insulin to supplement that which their bodies produce. About a quarter of type 2 patients rely on insulin treatment. In contrast to type 2 patients, individuals living with type 1 diabetes must rely on insulin treatments from the point of diagnosis until death.

89. If left untreated or under-treated, diabetes can become a debilitating and deadly disease. Indeed, it remains the seventh leading cause of death in the United States despite the availability of effective treatment. People with diabetes are almost twice as likely to have heart disease or a heart attack and 1.5 times more likely to have a stroke as those without the disease. Chronic kidney disease and failure is also much more common among those with diabetes. Furthermore, diabetes damages blood vessels and nerves, leading to serious, hard-to-treat infections and even amputations. Finally, the disease is the leading cause of blindness.

90. The explosion in diabetes prevalence has hit minorities and the poor the hardest. Type 2 diabetes disproportionately impacts African-Americans, American Indians, Asian Americans, Hispanics/Latinos and Pacific Islanders. For example, Native Americans are 420% more likely to die from diabetes-related causes of death than other Americans. With decreased access to nutritious food sources and fitness options, low income individuals are at a greater risk of obesity and, correspondingly, diabetes. These same demographic groups also account for a disproportionate share of the uninsured.

B. The Origins of Insulin Treatment

91. Despite its potentially deadly impact, diabetes is a highly treatable illness. For patients who are able to follow a prescribed treatment plan consistently, the harmful symptoms and health complications associated with the disease are entirely avoidable. And what's more, unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

92. A "widely celebrated tale of biomedical serendipity,"[31] the innovation of insulin treatment is revered for two reasons. First, the duo that discovered how to extract insulin for patient treatment was an unlikely pair: a young orthopedic surgeon without laboratory training, Frederick Banting, and his medical-student assistant, Charles Best. In 1922, the two men pioneered a technique for removing active insulin from an animal pancreas that could then be used to treat human patients with diabetes. Prior to this innovation, diabetes was almost always a death sentence.

93. However unlikely Banting and Best were as pharmaceutical innovators, the second reason for their fame is even more striking—especially to those familiar with the current pharmaceutical industry. At first, neither Banting nor Best applied for a patent on their game-changing innovation because they wanted their discovery to be open to the public, available to all. Ironically, they eventually ended up filing a patent to ensure access: Banting and Best realized that if they did not patent their drug, someone else would. To prevent others from obtaining exclusive rights and restricting supply, Banting and Best obtained a patent and then sold it to the University of Toronto for $1 each. As they wrote to the University's president, the patent was a form of publication: "When the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[32]

94. After selling their patent to the University of Toronto, university researchers attempted to manufacture insulin on campus. However, they quickly realized they lacked the expertise necessary to meet the demand of the North American market. Therefore, to scale production, the University of Toronto teamed up with Eli Lilly, "an established pharmaceutical

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[31] Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1171 (2015).
[32] M. Bliss, *The Discovery of Insulin* (2013).

company with experience producing glandular extracts."[33] Under this arrangement, Eli Lilly was allowed to apply for U.S. patents on any improvements to the manufacturing process. In addition to their contract with Eli Lilly, the Toronto team licensed the rights to produce insulin to a few other companies, including Denmark's Nordisk Insulinlaboratorium and Novo Terapeutisk Laboratorium.[34] Those initial licenses laid the groundwork for Eli Lilly and Nordisk's future domination of the insulin market.

95. Although the Toronto team's early iteration of insulin was immediately perceived as "a lifesaving drug of vast clinical public health significance,"[35] subsequent research led to further improvements in the drug's efficacy. The original animal insulin isolated by the Toronto team was short acting—it only had an effect on patient blood sugar levels for three to six hours. In the early 1930s, scientists at Nordisk discovered that the addition of a certain protein to insulin altered its absorption into the blood stream, prolonging its effect. This form of insulin became known as long-acting. A subsequent innovation in 1946—the addition of zinc to form the crystalline protamine-isophane insulin, now known as neutral protamine Hagedorn (NPH)—made it possible to combine long-acting and rapid-acting insulin. This advance allowed many diabetes patients to take a single daily injection. Soon afterward, a method for prolonging the action of insulin without adding protamine was discovered. These improvements offered important new options for the dosing of insulin. But they also extended the reach of insulin patents into the 1970s.

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[33] Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1171 (2015).
[34] Nordisk and Novo merged in 1989 to form Novo Nordisk.
[35] Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1172 (2015).

96. When the animal-based insulin patents finally began to expire, researchers made another leap forward in insulin technology. In the late 1970s, scientists began to produce human insulin through recombinant technology. By 1982, Eli Lilly brought the first recombinant human insulins—Humulin R (regular) and N (NPH)—to the U.S. market. Around the same time, Novo and Nordisk developed methods for chemically converting bovine insulin into human insulin. By 1988, a year prior to their merger, Novo and Nordisk obtained approval for their own recombinant insulin. This innovation allowed them to continue shared domination of the insulin market with Eli Lilly. It also enabled Eli Lilly and Novo Nordisk to spin a fresh web of insulin patents, promising to stretch into the 21st century.

97. After the introduction of human insulin, an improved understanding of the human genetic code and recombinant technology put a third insulin advance within reach. In the mid-1980s, scientists began to modify the molecular structure of insulin, attempting to improve its physiological effects. By 1996, Eli Lilly had obtained approval for Humalog, the first rapid-acting, man-made insulin. This new type of insulin—known as an analog—allowed for substantially faster absorption times. Never far behind Eli Lilly, Novo Nordisk released its own rapid-acting analog, Novolog, in 2000. Four years after that, a third pharmaceutical company, Sanofi-Aventis, released another rapid-acting analog, Apidra.

98. The same technological advances that brought about rapid-acting analogs also gave rise to long-acting analogs. In 2000, Sanofi released the first long-acting analog. This drug was branded as Lantus. Five years later, Novo Nordisk gained approval for its own long-acting analog, Levemir. The first patents on these long-acting analogs expired in June 2014, nearly a century after Banting and Best's first patent application in 1923.

Table 2: Insulin Available in the United States

Insulin Type	***Action***	***Brand Name***	***Generic Name***	***Company***
Human	**Rapid-acting**	Humulin R	Regular	Eli Lilly
		Novolin R	Regular	Novo Nordisk
	Intermediate	Humulin N	NPH (isophane)	Eli Lilly
		Novolin N	NPH (isophane)	Novo Nordisk
Analogs	**Rapid-acting**	Humalog	Lispro	Eli Lilly
		Novolog	Aspart	Novo Nordisk
		Apidra	Glulisine	Sanofi-Aventis
	Long-Acting	Lantus	Glargine	Sanofi-Aventis
		Levemir	Detemir	Novo Nordisk

C. Current Insulin Treatment Landscape

99. Today, analogs dominate the insulin market. Doctors and patients prefer analogs because they more closely mimic the way the human body naturally absorbs insulin released by the pancreas. As a result, it can be used in more flexible ways.

100. The American Diabetes Association—the organization responsible for setting guidelines for diabetes care in the United States—recommends analogs for treatment of individuals with both type 1 and type 2 diabetes.

101. For type 1 patients, insulin analogs are unquestionably the best course of treatment. Doctors uniformly prescribe analogs for type 1 patients.

102. For patients with type 2 diabetes, the American Diabetes Association describes long-acting analog insulin as the "most convenient initial insulin regimen."[36] Nonetheless, the organization notes that type 2 patients without a history of hypoglycemia (a condition caused by a drop in blood sugar level) can safely use cheaper, human insulins.

103. But doctors still prefer to prescribe analog insulins to type 2 patients. A recent study found that as of 2010, among adults who filled more than one prescription for insulin, 91.5% filled prescriptions for insulin analogs. The study found that percentage has grown considerably since 2000, when only 14.8% of patients (who filled more than one prescription for insulin) filled prescriptions for analog insulin. Now, type 2 patients use human insulin less frequently: the study found that only 14.8% of type 2 adults taking insulin filled a prescription for human insulin in 2010, down from 96.4% in 2000. As one specialist has observed, "[h]uman insulin has become almost entirely obsolete in private clinical practice."[37]

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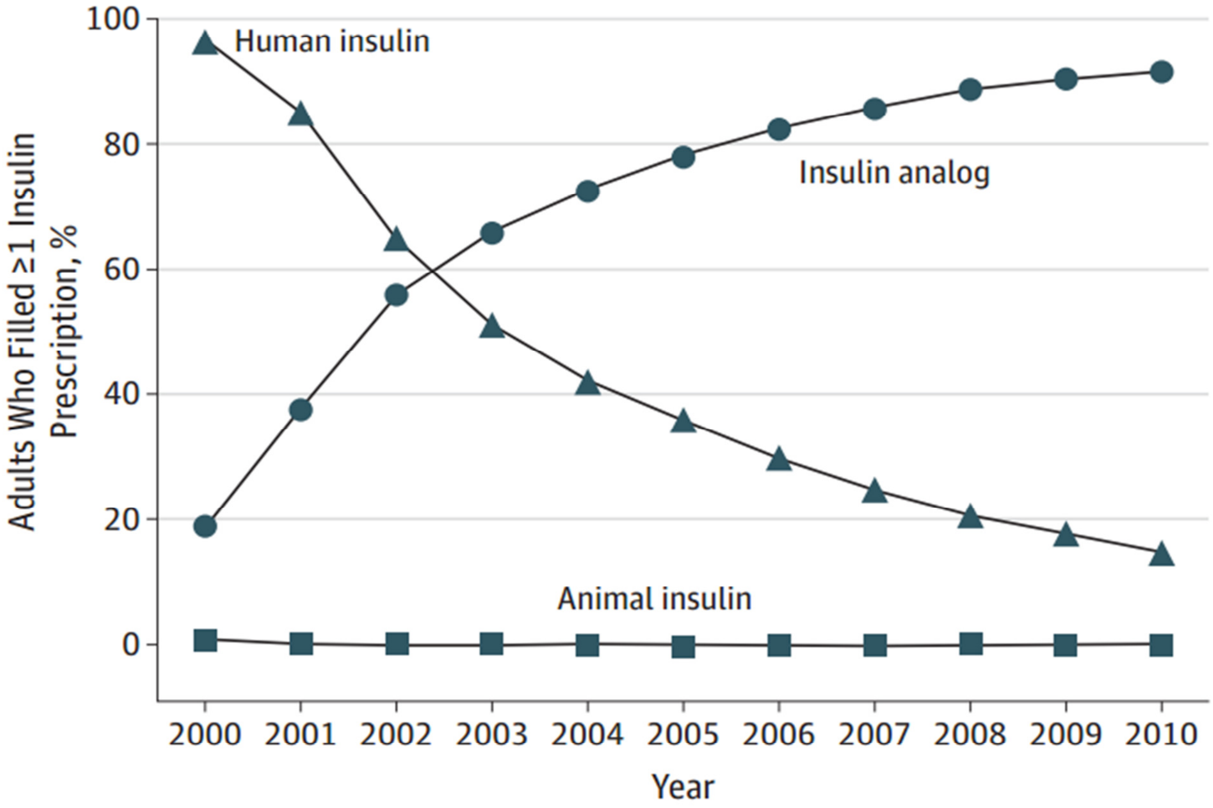
[36] American Diabetes Association, *Approaches to Glycemic Care*, 38 Diabetes Care S52, S57 (2016), http://care.diabetesjournals.org/content/39/Supplement_1/S52?ijkey=07291605370b0a3e07418e06fb5e894fb4314f05&keytype2=tf_ipsecsha.

[37] Allison Tsai, *The Rising Cost of Insulin*, Diabetes Forecast (Mar. 2016), http://www.diabetesforecast.org/2016/mar-apr/rising-costs-insulin.html?referrer=https://www.google.com/.

Figure 7: Type of Insulin Use Among U.S. Adults with Type 2 Diabetes (who filled more than one prescription)[38]


100
80
60
40
20
0
Human insulin
Insulin analog
Animal insulin
Adults Who Filled ≥1 Insulin Prescription, %
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
Year

104. Last year, the top three selling insulins were all analogs: Sanofi's long-acting Lantus garnered $6.98 billion in sales; Novo Nordisk's long-acting Novolog: $3.03; and Eli Lilly's rapid-acting Humalog: $2.84.

105. In December 2016, a third long-acting analog entered the market: Eli Lilly's Basaglar. Basaglar is a follow-on product to Lantus. However, it is not considered a generic drug because it did not rely on the Food, Drug, and Cosmetic Act's ("FDCA") Abbreviated New Drug Application pathway—the normal pathway to generic entry—for approval. Instead, Basaglar was approved under a different FDCA pathway as a follow-on medication.

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[38] Kasia Lipska, et al., *Use and Out-of-Pocket Costs of Insulin for Type 2 Diabetes Mellitus from 2000 to 2010*, 311 J. Am. Med. Ass'n 2331, 2332 (2014).

D. Climbing Insulin Prices Unrelated to Any Rise in Production Costs

106. Despite the availability of a number of highly effective insulin drugs, too many people living with diabetes go without proper treatment for an all too familiar reason: cost.

107. Sanofi's benchmark price—also known as a sticker price—for Lantus, the top-selling analog insulin, now sits at about $250 per vial, up from about $115 in 2011. The average diabetes patient needs one vial of insulin per month. Therefore, Lantus costs an average patient about $250 per month if they buy at sticker price. However, many patients need much more than one vial per month, so that cost can be much higher.

108. Novo Nordisk's current benchmark price for Levemir is now about $280 per vial, up from about $90 in 2011. Novo Nordisk's benchmark price for Novolog now sits at about $250 per vial, up from about $100 in 2011. Thus, the average Levemir user spends about $280 per month and the average Novolog user spends $250 based on sticker price.

109. Eli Lilly has raised the benchmark price of Humalog to about $255 per vial, more than double the 2011 price. Thus, the average Humalog patient purchasing at benchmark price spends about $255 per month.

110. But the benchmark prices of insulin analogs have not always been so high. In just the last five years, Sanofi and Novo Nordisk have raised Lantus and Levemir's sticker prices an astounding 168% and 169%, respectively.[39] In fact, last year, Novo Nordisk and Sanofi were responsible for the highest drug benchmark price increases in the *entire* industry.[40] This distinction largely reflected their price hikes for Lantus and Levemir: Sanofi and Novo Nordisk

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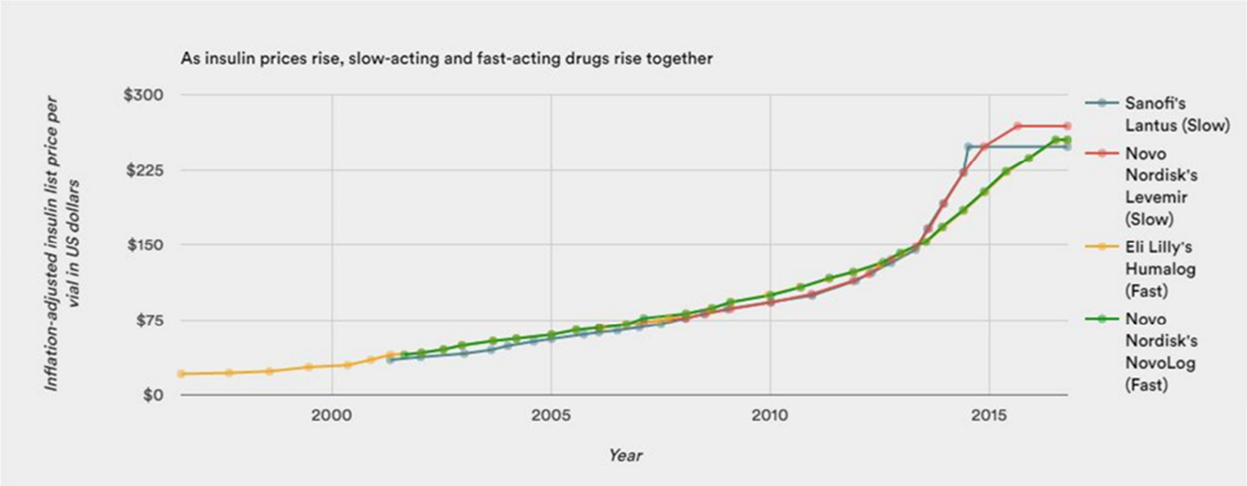
[39] Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2016), http://www.bloomberg.com/news/articles/2015-05-06/diabetes-drugs-compete-with-prices-that-rise-in-lockstep; Allison Tsai, *The Rising Cost of Insulin*, Diabetes Forecast (Mar. 2016), http://www.diabetesforecast.org/2016/mar-apr/rising-costs-insulin.html?referrer=https://www.google.com/.

[40] Credit Suisse Report.

raised the benchmark prices of those drugs by 30% over the course of 2014.[41] Figure 8 shows Sanofi, Novo Nordisk, and Eli Lilly's exponential benchmark price hikes from 2000 to 2015.

Figure 8: Rapid Rising Insulin Benchmark Prices from 2000-2015[42]


As insulin prices rise, slow-acting and fast-acting drugs rise together
Inflation-adjusted insulin list price per vial in US dollars
$300
$225
$150
$75
$0
2000
2005
2010
2015
Year
Sanofi's Lantus (Slow)
Novo Nordisk's Levemir (Slow)
Eli Lilly's Humalog (Fast)
Novo Nordisk's NovoLog (Fast)

111. Sanofi, Novo Nordisk, and Eli Lilly have not only dramatically increased their insulins benchmark prices in the last 10 years, they have done so in perfect lock-step. In 13 instances since 2009, Sanofi and Novo Nordisk raised the benchmark prices of their long-acting analog insulins, Lantus and Levemir, in tandem, "taking the same price increase down to the decimal point within a few days of each other."[43] As one healthcare analyst put it: "That is pretty much a clear signal that your competitor doesn't intend to price-compete with you."[44] Eli Lilly and Novo Nordisk have engaged in the same lock-step behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figures 9 and 10 demonstrate this seemingly

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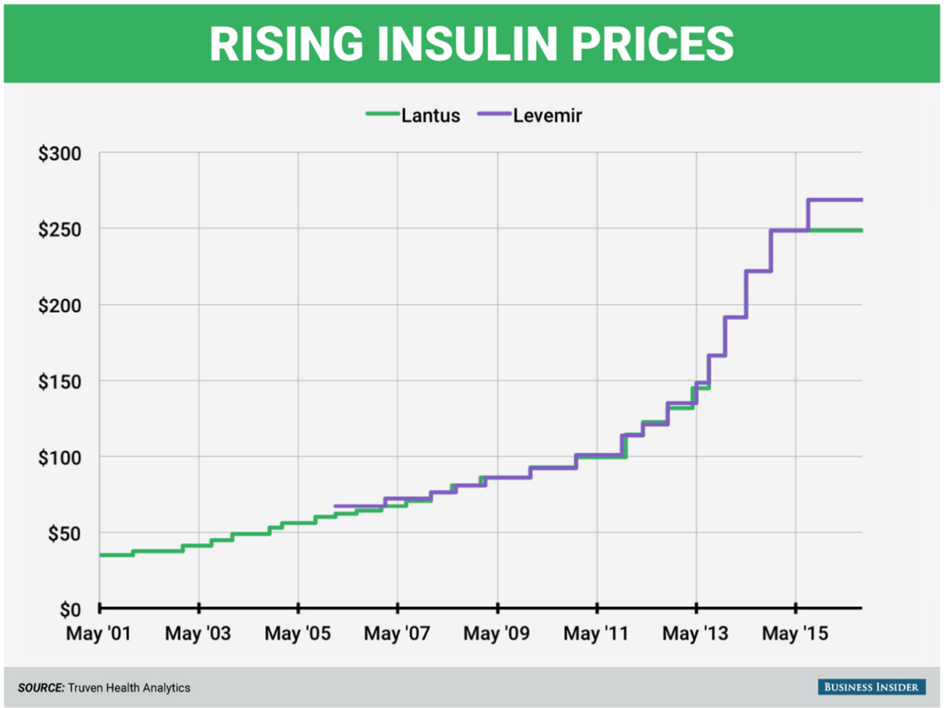
[41] Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2016), http://www.bloomberg.com/news/articles/2015-05-06/diabetes-drugs-compete-with-prices-that-rise-in-lockstep.
[42] Rebecca Robbins, *The Insulin Market is Heading for a Shakeup. But Patients May Not Benefit*, STAT (Oct. 14, 2016), https://www.statnews.com/2016/10/14/insulin-prices-generics/.
[43] Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2016), http://www.bloomberg.com/news/articles/2015-05-06/diabetes-drugs-compete-with-prices-that-rise-in-lockstep.
[44] *Id.*

collusive behavior with respect to Lantus and Levemir; Figure 9 demonstrates this behavior with respect to Humalog and Novolog.

Figure 9: Rising Lantus and Levemir Benchmark Prices from 2001-2015[45]


RISING INSULIN PRICES
Lantus
Levemir
$300
$250
$200
$150
$100
$50
$0
May '01
May '03
May '05
May '07
May '09
May '11
May '13
May '15
SOURCE: Truven Health Analytics
BUSINESS INSIDER

[45] Lydia Ramsey, *A 93-year-old Drug that Can Cost more than a Mortgage Payment Tells Us Everything that's Wrong with American Healthcare*, Business Insider (Sept. 16, 2016), http://www.businessinsider.com/insulin-prices-increase-2016-9.

Figure 10: Sanofi and Novo Nordisk Increase Benchmark Prices in Lock-Step[46]

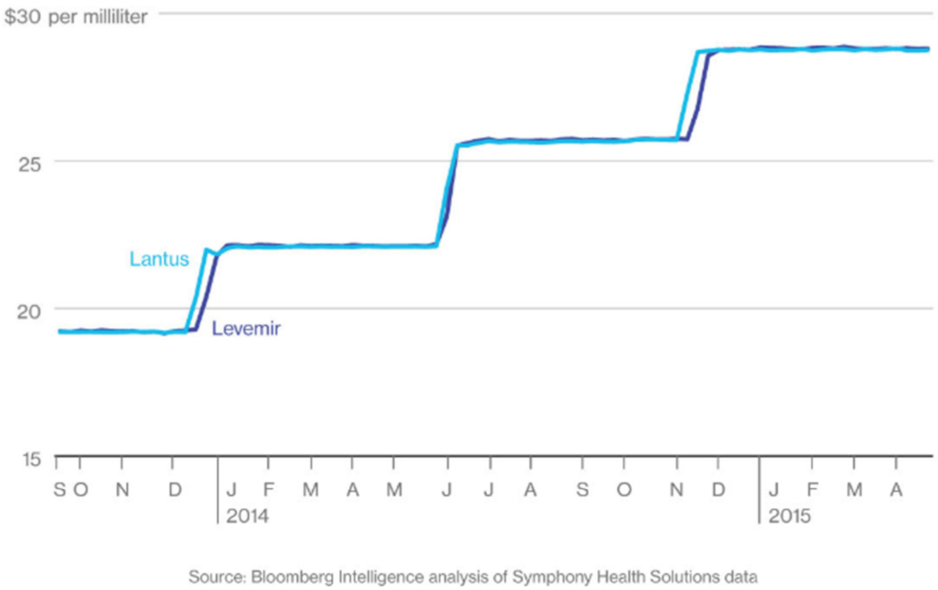
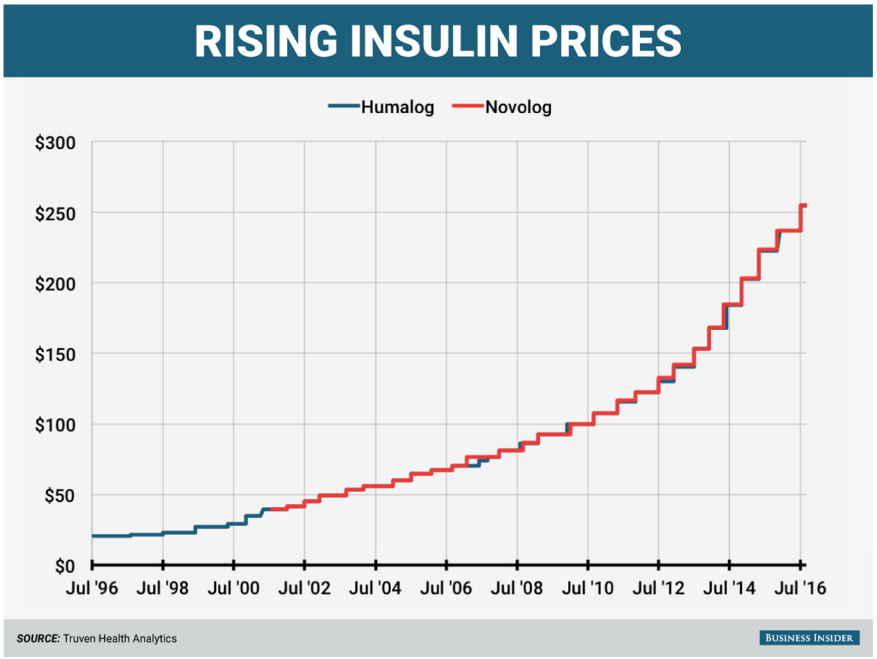

$30 per milliliter
25
20
15
Lantus
Levemir
S O N D J F M A M J J A S O N D J F M A
2014
2015
Source: Bloomberg Intelligence analysis of Symphony Health Solutions data

Figure 11: Eli Lilly and Novo Nordisk Increase Benchmark Prices in Lock-Step[47]


RISING INSULIN PRICES
Humalog
Novolog
$300
$250
$200
$150
$100
$50
$0
Jul '96 Jul '98 Jul '00 Jul '02 Jul '04 Jul '06 Jul '08 Jul '10 Jul '12 Jul '14 Jul '16
SOURCE: Truven Health Analytics
Business Insider

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[46] Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2016), http://www.bloomberg.com/news/articles/2015-05-06/diabetes-drugs-compete-with-prices-that-rise-in-lockstep.

[47] Lydia Ramsey, *A 93-year-old Drug that Can Cost more than a Mortgage Payment Tells Us Everything that's Wrong with American Healthcare*, Business Insider (Sept. 16, 2016), http://www.businessinsider.com/insulin-prices-increase-2016-9.

E. Collusive Competition: The Real Reason for Sanofi and Novo Nordisk's Increasing Benchmark Prices

112. To an outside observer, Sanofi, Novo Nordisk, and Eli Lilly's behavior does not add up. As direct market competitors, why have these companies raised their prices in lock step instead of undercutting each other's prices in the way firms do in normal competitive markets?

113. In the past, Novo Nordisk maintained that their price increases reflected the "clinical benefit"[48] of their drugs. But Lantus, Levemir, Novolog, and Humalog are the exact same drugs that they were 10 years ago—their clinical benefits have not changed. Where clinical benefit has not changed, it cannot be used to justify a 169% price increase. Therefore, another factor motivates these benchmark prices increases.

114. The real reason Sanofi, Novo Nordisk, and Eli Lilly have not undercut each other's benchmark prices is because these firms are competing on a hidden index: spread. PBMs control the formularies that determine whether people living with diabetes will purchase Sanofi, Eli Lilly, or Novo Nordisk's drugs. To secure a position on the PBMs' formularies, these companies have artificially inflated their list price.

115. While this practice benefits both drug companies and PBMs, it harms consumers. They shoulder the burden of the higher benchmark prices, paying more out-of-pocket for their insulins.

116. Under pressure to explain its rising benchmark prices, Novo Nordisk admitted to this behavior in a recent press release. On November 30, 2006, Novo Nordisk issued a press release stating:

> We hear from more and more people living with diabetes about the challenges they face affording healthcare, including the medicines we

[48] Allison Tsai, *The Rising Cost of Insulin*, Diabetes Forecast (Mar. 2016), *available at* http://www.diabetesforecast.org/2016/mar-apr/rising-costs-insulin.html?referrer=https://www.google.com/.

> make. . . . News reports on drug prices have left the public with an impression that companies like ours realize all the profits from the "[benchmark] price" increases we've made over the last decade. In other words, a [benchmark] price increase by **XX percent leads to an automatic XX percent profit** for the drug maker. We believe that is misleading and here's why: As the manufacturer, we do set the "[benchmark] price" and have full accountability for those increases. However, after we set the [benchmark] price, we negotiate with the companies that actually pay for the medicines, which we call payers. This is necessary in order for our medicines to stay on their preferred drug list or formulary. The price or profit we receive after rebates, fees and other price concessions we provide to the payer is the "net price." The net price more closely reflects our actual profits.[49]

117. Explaining the company's benchmark price increases, Novo Nordisk directly admitted that it "set[s] [benchmark] price" with an eye to achieving "preferred" formulary status.

118. Eli Lilly, too, has admitted that it raises benchmark prices as a *quid pro quo* for formulary positions: "The reason drugmakers sharply raise benchmark prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists."[50]

119. But these explanations omit a crucial detail: drug companies could offer PBMs the same high rebates in a manner that would help consumers: they could lower their real prices, instead of inflating benchmark price. Increasing spreads in this manner would benefit consumers. Yet the insulin manufacturers refuse to significantly lower their real prices, and the PBMs continue to accept this behavior so long as benchmark prices continue to rise while real prices stay constant.

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[49] Novo Nordisk Press Release (Nov. 30, 2016), http://press.novonordisk-us.com/leadership-perspectives?item=1.

[50] Denise Roland & Peter Loftus, *Middlemen Fuel Insulin Price Rise*, Wall St. J., Oct. 10, 2016, at B1.

120. In furtherance of this scheme, Novo Nordisk has steeply raised the benchmark prices of Levemir and Novolog while keeping the real prices of these drugs constant. Figures 12 and 13—included in Novo Nordisk's press release—illustrate this conduct.

Figure 12: Novolog Vial Real Versus Benchmark Price Increases[51]

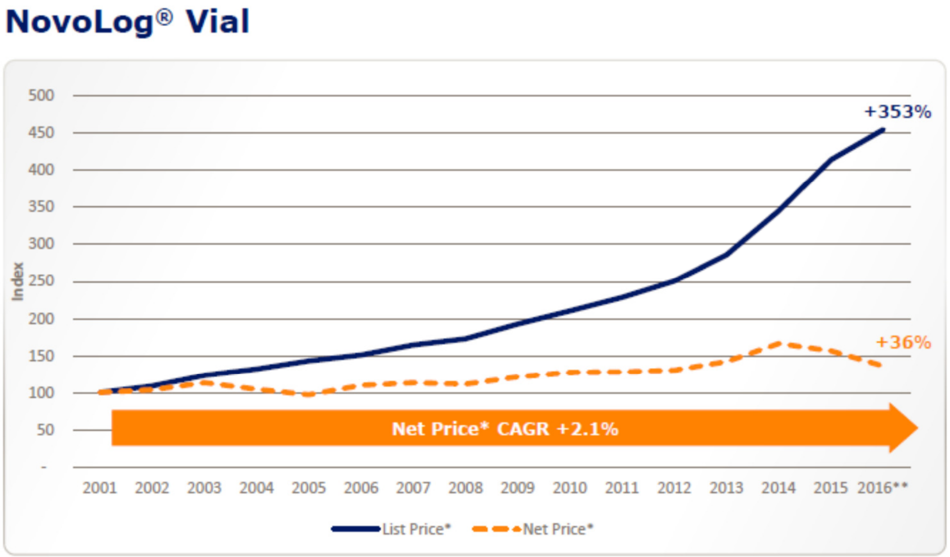
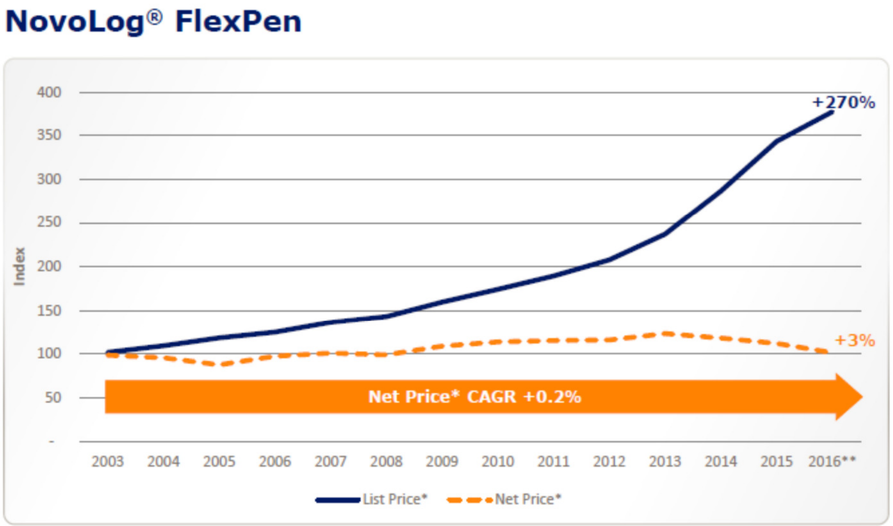

NovoLog® Vial
Index
500
450
400
350
300
250
200
150
100
50
-
+353%
+36%
Net Price* CAGR +2.1%
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016**
List Price*
Net Price*

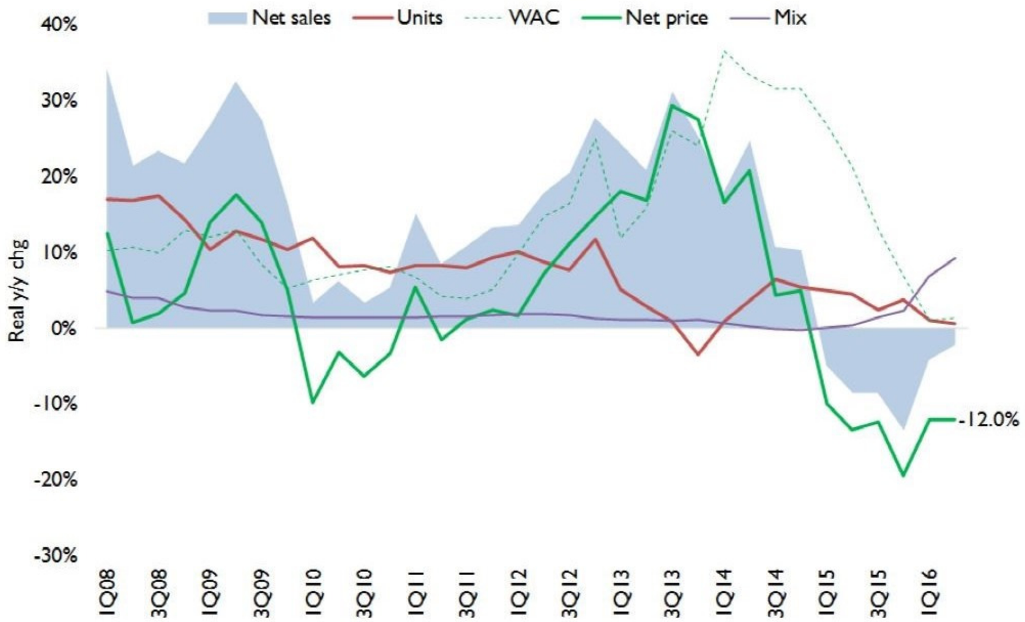
Figure 13: Novolog FlexPen[52] **Real Versus Benchmark Price Increases**[53]


NovoLog® FlexPen
Index
400
350
300
250
200
150
100
50
-
+270%
+3%
Net Price* CAGR +0.2%
2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016**
List Price*
Net Price*

[51] Novo Nordisk Press Release (Nov. 30, 2016), http://press.novonordisk-us.com/leadership-perspectives?item=1.
[52] The FlexPen is a type of insulin injection. Patients who use this pen stick themselves with a pen-like insulin distributor instead of injection insulin through a pump.
[53] *Id.*

121. Overall, the sales-weighted net prices for the long-acting insulins fell 12% in 2016. Figure 14 illustrates this phenomenon.

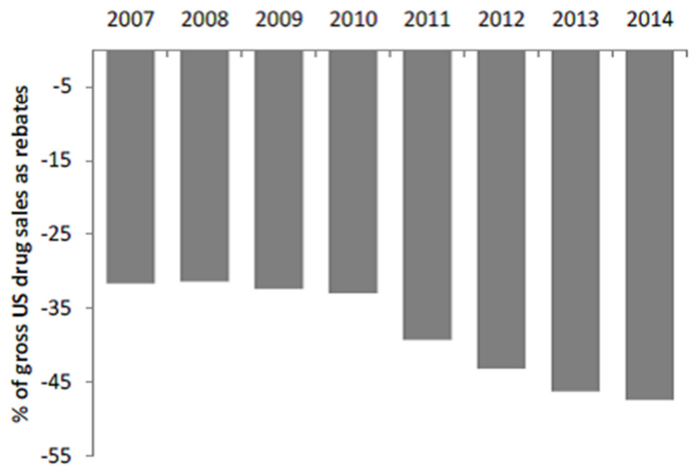
Figure 14: Difference between Benchmark and Net Price for Long-Acting Insulins from 2008-2016[54]


Net sales
Units
WAC
Net price
Mix
Real y/y chg
40%
30%
20%
10%
0%
-10%
-20%
-30%
-12.0%
1Q08
3Q08
1Q09
3Q09
1Q10
3Q10
1Q11
3Q11
1Q12
3Q12
1Q13
3Q13
1Q14
3Q14
1Q15
3Q15
1Q16

122. Sanofi, Novo Nordisk, and Eli Lilly's spread-increasing behavior is also visible from data on these companies' rebates to PBMs and insurers. The two figures below illustrate Novo Nordisk's rebates from 2007 to 2014.

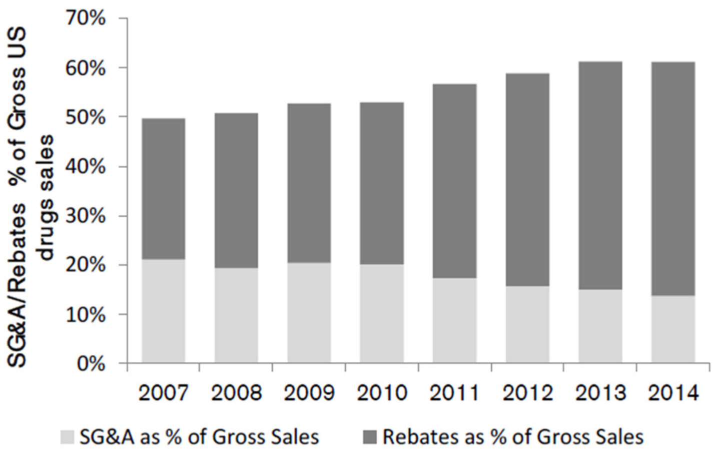
[54] Richard Evans, Scott Hinds, & Ryan Baum, *US Rx Net Pricing Trends Thru 2Q16*, SSR LLC, 36 (Oct. 5, 2016).

Figure 15: Novo Nordisk's Reported Rebates as a Percentage of U.S. Gross Sales from 2007-2014[55]


2007
2008
2009
2010
2011
2012
2013
2014
% of gross US drug sales as rebates
-5
-15
-25
-35
-45
-55

Source: Company data, Credit Suisse estimates

Figure 16: Novo Nordisk's Selling, General, and Administrative Costs and Rebates as a Percentage of Gross U.S. Sales from 2007-2014[56]

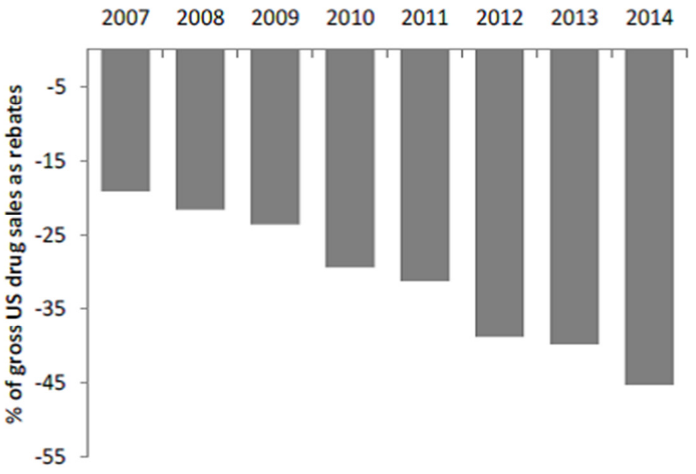

SG&A/Rebates % of Gross US drugs sales
70%
60%
50%
40%
30%
20%
10%
0%
2007
2008
2009
2010
2011
2012
2013
2014
SG&A as % of Gross Sales
Rebates as % of Gross Sales

Source: Company data, Credit Suisse estimates

123. Sanofi has also greatly increased its spreads. Figures 17 and 18 show the amount Sanofi has increased its rebates (spreads) from 2007 to 2014.

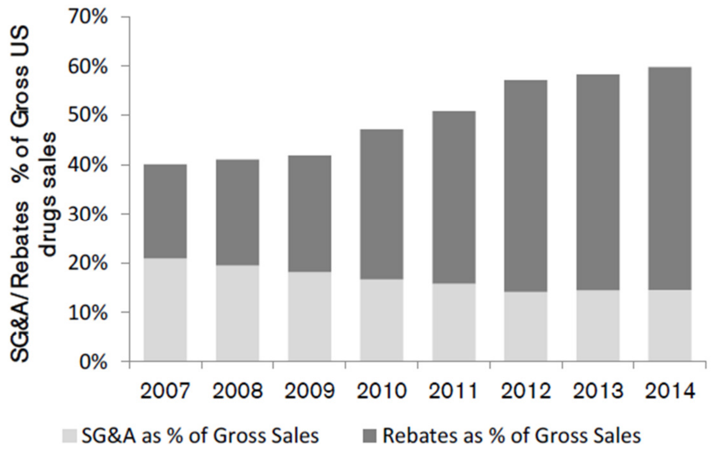
[55] Jeffrey Balin, et al., *Global Pharma: Rising US Rebates Limit Margin Expansion*, Credit Suisse, 23 (May 1, 2015).
[56] *Id.*

Figure 17: Sanofi's Reported Rebates as a Percentage of U.S. Gross Sales from 2007-2014[57]


2007
2008
2009
2010
2011
2012
2013
2014
% of gross US drug sales as rebates
-5
-15
-25
-35
-45
-55

Source: Company data, Credit Suisse estimates

Figure 18: Sanofi's Selling, General, and Administrative Costs and Rebates as a Percentage of Gross U.S. Sales from 2007-2014[58]


SG&A/Rebates % of Gross US drugs sales
70%
60%
50%
40%
30%
20%
10%
0%
2007
2008
2009
2010
2011
2012
2013
2014
SG&A as % of Gross Sales
Rebates as % of Gross Sales

Source: Company data, Credit Suisse estimates

124. Finally, Eli Lilly has greatly increased its spreads. Figures 19 and 20 show the amount Eli Lilly has increased its rebates (spreads) from 2007 to 2014.

Figure 19: Eli Lilly's Reported Rebates as a Percentage of U.S. Gross Sales from 2007-

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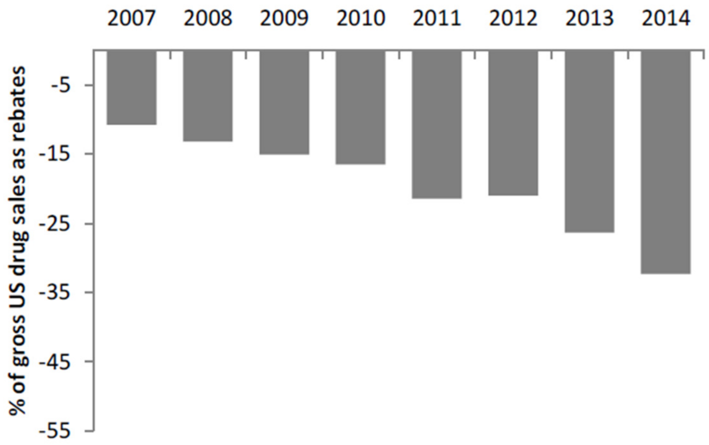
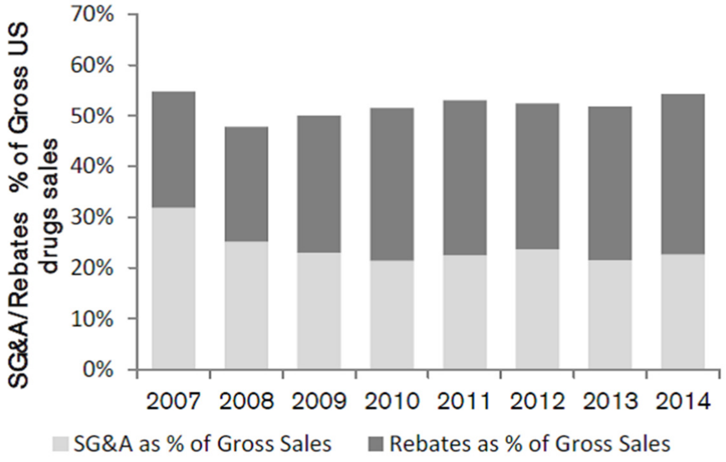
[57] *Id.* at 26.
[58] *Id.*

2014[59]


2007
2008
2009
2010
2011
2012
2013
2014
% of gross US drug sales as rebates
-5
-15
-25
-35
-45
-55

Source: Company data, Credit Suisse estimates

Figure 20: Eli Lilly's Selling, General, and Administrative Costs and Rebates as a Percentage of Gross U.S. Sales from 2007-2014[60]


SG&A/Rebates % of Gross US drugs sales
70%
60%
50%
40%
30%
20%
10%
0%
2007
2008
2009
2010
2011
2012
2013
2014
SG&A as % of Gross Sales
Rebates as % of Gross Sales

Source: Company data, Credit Suisse estimates

125. Sanofi and Novo Nordisk have stretched the spreads on their analog insulin medications to the point where they have become the second and third largest rebators in the entire pharmaceutical industry. In an industry where artificial benchmark prices inflation has become common, Sanofi, Novo Nordisk, and Eli Lilly are three of the worst offenders.

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[59] *Id.* at 17.
[60] *Id.*

126. Over the last 10 years, diabetes patients who need analog insulins have been paying higher and higher benchmark prices for Lantus, Levemir, Novolog, and Humalog. But, in reality, the real prices of these medications to PBMs are staying constant (and even slightly dropping). The vast majority of diabetes patients have no idea that the benchmark prices they struggle to afford are not only different from the prices PBMs and insurers receive, but actually trend in entirely different direction. As the benchmark prices of Lantus, Levemir, Novolog, and Humalog slide further and further away from their real, net prices, these benchmark prices become so misrepresentative, so untethered from the reality as to be fraudulent. And while this practice enables Sanofi, Novo Nordisk, and Eli Lilly to offer larger rebates to some PBMs (and, as a result, insurers), it does so at the price of access. The uninsured and underinsured—by definition, some of the most vulnerable populations in the United States—cannot afford the artificial prices that Sanofi, Novo Nordisk, and Eli Lilly offer.

F. The Economic Effect of Sanofi, Novo Nordisk, and Eli Lilly's Price Increases on Patients

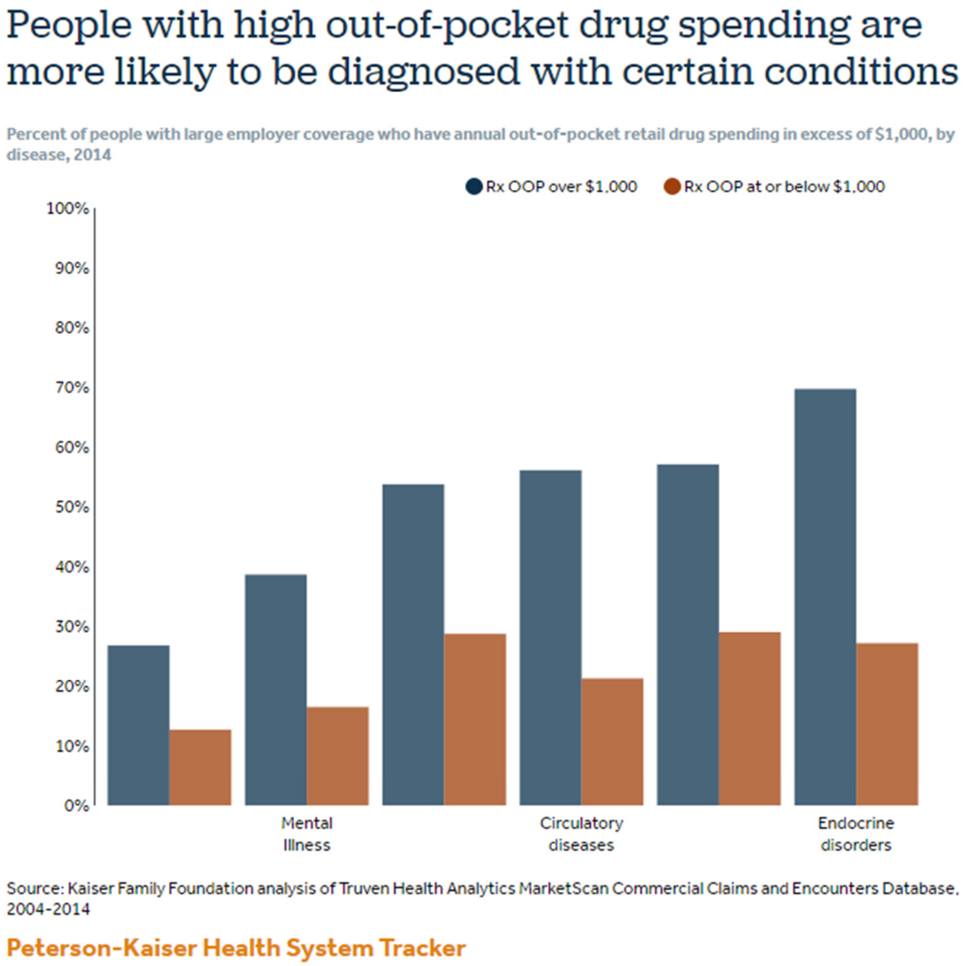
127. As previously explained, Sanofi, Novo Nordisk, and Eli Lilly's price hikes have hit a number of patient groups particularly hard—the uninsured, those with high deductibles, those with high coinsurance rates, and those who hit the Medicare Part D Donut Hole.

128. Currently, 150 million Americans get healthcare insurance through their employers. Increasingly, individuals within this group are unable to afford their prescribed insulins due to the cost-sharing obligations their health plans impose. A 2014 study found that among patients with commercial insurance, out-of-pocket costs for people with type 2 diabetes rose a staggering 89% from 2000 to 2010.[61]

[61] Kasia Lipska, et al., *Use and Out-of-Pocket Costs of Insulin for Type 2 Diabetes Mellitus from 2000 to 2010*, 311 J. Am. Med. Ass'n 2331, 2332 (2014).

129. In fact, patients with endocrine disorders, such as diabetes, are more likely to shoulder out-of-pocket costs in excess of $1,000 than patients *in any other disease class*. As Figure 21 illustrates, 70% of people with endocrine disorders have out-of-pocket drug spending at or above $1,000.

Figure 21: Conditions that Are More Likely to Lead to High Out-of-Pocket Spending[62]


People with high out-of-pocket drug spending are more likely to be diagnosed with certain conditions
Percent of people with large employer coverage who have annual out-of-pocket retail drug spending in excess of $1,000, by disease, 2014
Rx OOP over $1,000
Rx OOP at or below $1,000
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Mental Illness
Circulatory diseases
Endocrine disorders
Source: Kaiser Family Foundation analysis of Truven Health Analytics MarketScan Commercial Claims and Encounters Database, 2004-2014
Peterson-Kaiser Health System Tracker

130. The increasing number of patients with high-deductible plans and coinsurance obligations, together with the rise in coinsurance rates, has made the pain associated with the Lantus, Levemir, Humalog, and Novolog price hikes particularly acute. Although insulin has

[62] Cynthia Cox, et al., *Examining High Prescription Drug Sending for People with Employer Sponsored Health Insurance*, Kaiser Family Foundation (Oct. 27, 2016), http://www.healthsystemtracker.org/insight/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/.

been available for over 100 years, Sanofi, Novo Nordisk, and Eli Lilly's price hikes are now making it harder than ever to obtain.

III. The Real Impact of Artificial Pricing

131. For many Plaintiffs and Class members, Sanofi, Novo Nordisk, and Eli Lilly's artificial price inflation has cost them their health, financial stability, and emotional wellbeing. Unable to afford Sanofi, Novo Nordisk, and Eli Lilly's price increases, many patients have begun to engage in highly risky behaviors with respect to their disease. Plaintiffs report under-dosing their insulin, skipping their refills, injecting expired insulin, and avoiding doctors' visits. To compensate for their lack of insulin, some patients starve themselves, forgo one or even two meals a day. These practices—which ineffectively control blood sugar levels—can lead to serious complications such as kidney disease and failure, heart disease and heart attacks, infection, amputation, and blindness. One class member with type 1 diabetes has been unable to afford the Levemir her doctor prescribes and has been taking human insulin instead. The human insulin, however, does not effectively control her blood sugar levels and she has been progressive loosing feeling in her foot. She worries she may eventually lose it if she does not find a way to obtain Levemir at a lower cost. Ineffective control of blood sugar can also cause sustained hyperglycemia and, in severe cases, diabetic ketoacidosis, which can be life-threatening. Other Plaintiffs explain that their insulin costs have left them unable to afford the healthy diets they should be maintaining. While analog insulin should be improving the health of Plaintiffs, Defendants' price hikes have had led to the opposite effect.

132. But the toll of Defendants' price hikes is not just physical: the high cost of insulin causes serious financial difficulty and emotional stress. Multiple class members spend over 50% of their income on their insulin drugs. The financial burden stress can be all

consuming: many class members describe a constant state of anxiety brought on by their inability to afford the cost of rising insulin prices.

133. PBMs and insurers claim that their scheme of discounts and rebates ultimately benefits plan enrollees by providing them with lower drug costs. Even assuming that some part of the discounts does reach insured patients (after the PBMs and insurers have both taken their cuts), these discounts are never redistributed to uninsured patients. It also does not come back to under-insured patients—those in plans with high deductibles and coinsurance obligations—who must pay much of their prescription drug costs out-of-pocket. Many patients cannot afford to hit their deductibles year after year. They must begin to ration their insulin before they hit their deductibles and their insurers begin to kick in for their insulin costs.

134. Cognizant of the damage increasing benchmark prices have inflicted on patients, Novo Nordisk and Eli Lilly have recently announced that they will take steps, going forward, to rein in this harm. In its November 30, 2016 press release, Novo Nordisk made a modest commitment to "limit[] any potential future benchmark price increases for our medicines to no more than single-digit percentages annually." On December 13, 2016, Eli Lilly announced that, starting on January 1, patients who pay full-retail prices out of pocket for Eli Lilly's insulin will gain access to 40% discounts on their Eli Lilly's insulins.

135. Long overdue, these affordability measures still do not end or even address the insidious practice of competing for PBM business based on the spread between benchmark and net price. Nor do they make whole the patients who have spent thousands of dollars out-of-pocket on long acting insulins for the past few years. Therefore, these measures fail to address the structural issues that have given rise to the price hikes that have hurt under-insured and uninsured diabetes patients for years.

136. Individuals living with diabetes spend, on average, twice as much as those without the disease despite the fact that treatment for the disease has existed for over 100 years. Diagnosed diabetes now costs the United States over $245 billion per year: an estimated $1 of every $5 spent on health care in the United States. Sanofi, Novo Nordisk, and Eli Lilly's artificial inflation of insulin analog prices has pushed and will continue to push access to life-saving drugs out of reach of uninsured and underinsured American diabetes patients, even despite recent efforts to control prices. Without access to proper treatment, diabetes patients experience serious and costly health complications. Despite the efforts of the original insulin innovators to ensure the drug was widely accessible, the pharmaceutical companies that have inherited their legacy have eschewed this aspiration, sublimating it to the companies' profit margins. The fraudulent practice of creating a large spread between benchmark and real prices has harmed and will continue to harm diabetes patients across the country. Millions more will suffer painful complications and early death unless Sanofi, Novo Nordisk, and Eli Lilly make analog insulin more affordable.

TOLLING OF THE STATUTE OF LIMITATIONS

I. Discovery Rule Tolling

137. Plaintiffs and Class members had no way of knowing about Defendants' scheme and deception with respect to insulin pricing.

138. PBM's refuse to disclose the real costs of insulin, labeling them trade secrets, hence a reasonable plaintiff and consumer could not discover the truth.

139. Within the time period of any applicable statutes of limitation, Plaintiffs and members of the proposed class could not have discovered through the exercise of reasonable diligence that Defendants were concealing the conduct complained of herein and misrepresenting the true cost of insulin.

140. Plaintiffs and the other Class members did not discover, and did not know of facts that would have caused a reasonable person to suspect, that Defendants were engaged in the scheme and were publishing phony benchmark prices, nor would reasonable and diligent investigation have disclosed the true facts.

141. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule with respect to claims as to all vehicles identified herein.

II. Fraudulent Concealment Tolling

142. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time period relevant to this action.

III. Estoppel

143. Defendants were under a continuous duty to disclose to Plaintiffs and Class members the true character, quality, and nature of the benchmark prices upon which their payments for insulin were based.

144. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

CLAIMS FOR RELIEF

COUNT ONE: Violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* against Novo Nordisk

145. Plaintiffs repeat and incorporate by reference all preceding and succeeding paragraphs and allegations.

146. This claim is brought on behalf of the class against Novo Nordisk for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1962 *et seq.*

147. Defendant is a "person" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

148. Plaintiffs and the members of the class are each "persons," as that term is defined in 18 U.S.C. § 1961(3) who were injured in their business or property as a result of Novo Nordisk's wrongful conduct.

A. The Levemir/Novolog Pricing Enterprise

149. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.

150. Novo Nordisk formed just such an association-in-fact enterprise—sometimes referred to in this complaint as the Levemir/Novolog Pricing Enterprise. The Levemir/Novolog Pricing Enterprise consists of (a) Novo Nordisk, including its employees and agents; (b) the PBM CVS Caremark, including its employees and agents; (c) the PBM Express Scripts, including its employees and agents; and (d) the PBM OptumRx, including its employees and agents.

151. The Levemir/Novolog Pricing Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to secure an exclusive, or at least favorable, formulary position for Novo Nordisk's long-acting analog insulin product, Levemir, and its rapid-acting analog insulin product, Novolog, as a treatment for type 1 and 2 diabetes to the exclusion or detriment of competitor products and consumers.

152. To accomplish this purpose, the Levemir/Novolog Pricing Enterprise periodically and systematically inflated the benchmark prices of Levemir and Novolog and represented—either affirmatively or through half-truths and omissions—to the general public, health care payers, and consumers, including Plaintiffs and the class, that Levemir and Novolog' s benchmark prices fairly and accurately reflected the actual cost of this drug. The Enterprise concealed from the public, health care payers, and consumers, like Plaintiffs and the class members, the existence and amount of steep rebates Novo Nordisk gave to the PBMs. These rebates were worth at least 25% of the benchmark price. The Levemir/Novolog Pricing Enterprise also concealed from the public the purpose of these rebates: The difference between the benchmark price and the real prices of Levemir and Novolog negotiated by the PBMs resulted in increased profits for the PBMs. These large rebates served to ensure that the PBMs would place, and maintain, Levemir and Novolog in a preferred or favorable position on the PBMs' formularies. By securing a favorable position on the formulary, the Levemir/Novolog Pricing Enterprise ensured that a larger number of Levemir and Novolog prescriptions would be written and filled. This scheme translated into higher sales (and therefore profits) for Novo Nordisk and larger spreads for the PBMs.

153. The persons engaged in the Levemir/Novolog Pricing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Novo Nordisk. There is regular communication between Novo Nordisk and each of the PBMs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Novo Nordisk and the PBMs share information regarding the Levemir and Novolog benchmark prices and discuss and agree on rebate amounts. Novo Nordisk and the PBMs

functioned as a continuing unit for the purposes of implementing the Levemir and Novolog pricing scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

154. At all relevant times, CVS Caremark was aware of Novo Nordisk's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. CVS Caremark struck rebate deals with Novo Nordisk to conceal the true prices of Levemir and Novolog and profit from the inflated rebates. CVS Caremark represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the costs of Levemir and Novolog for consumers, because the published benchmark price was falsely inflated. CVS Caremark also knew, but did not disclose, that the other PBMs—Express Scripts and OptumRx—were engaged in the same rebating scheme, to the detriment of consumers. But for the Levemir/Novolog Pricing Enterprise's unlawful fraud, CVS Caremark would have had the incentive to disclose the deceit by Novo Nordisk, thereby forcing competition on real price. By failing to disclose this information, CVS Caremark perpetuated the Levemir/Novolog Pricing Enterprise's scheme, and reaped substantial profits.

155. At all relevant times, Express Scripts was aware of Novo Nordisk's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. Express Scripts struck rebate deals with Novo Nordisk to conceal the true prices of Levemir and Novolog and profit from the inflated rebates. Express Scripts represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the costs of Levemir and Novolog for consumers, because the published benchmark

price was falsely inflated. Express Scripts also knew, but did not disclose, that the other PBMs—CVS Caremark and OptumRx—were engaged in the same rebating scheme, to the detriment of consumers. But for the Levemir/Novolog Pricing Enterprise's unlawful fraud, Express Scripts would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, Express Scripts perpetuated the Levemir/Novolog Pricing Enterprise's scheme, and reaped substantial profits.

156. At all relevant times, OptumRx was aware of Novo Nordisk's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. OptumRx struck rebate deals with Novo Nordisk to conceal the true prices of Levemir and Novolog and profit from the inflated rebates. OptumRx represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the costs of Levemir and Novolog for consumers, because the published benchmark price was falsely inflated. OptumRx also knew, but did not disclose, that the other PBMs—CVS Caremark and Express Scripts—were engaged in the same rebating scheme, to the detriment of consumers. But for the Levemir/Novolog Pricing Enterprise's unlawful fraud, OptumRx would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, OptumRx perpetuated the Levemir/Novolog Pricing Enterprise's scheme, and reaped substantial profits.

157. Furthermore, as public scrutiny, media coverage, and congressional investigations have focused on the rapidly-inflating prices of lifesaving drugs—including insulin—the PBMs did not challenge Novo Nordisk's reported benchmark prices, terminate their

role in the Levemir/Novolog Pricing Enterprise, nor disclose publicly that the Levemir and Novolog benchmark prices did not accurately reflect the price actually paid for the drugs.

158. CVS Caremark, Express Scripts, and OptumRx participated in the conduct of the Levemir/Novolog Pricing Enterprise, sharing the common purpose of securing exclusive or favorable formulary positions for Levemir and Novolog, through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and (5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343. The PBMs knowingly made material misstatements to health care payers, plan members, and the general public in furtherance of the fraudulent scheme regarding:

a. The actual prices of Levemir and Novolog;

b. The extent to which the actual prices of Levemir and Novolog departed from the published, artificially-inflated benchmark prices;

c. The extent to which Novo Nordisk and the PBMs had negotiated the rebates discounting the benchmark prices of Levemir and Novolog in good faith and for a proper purpose;

d. Whether the rebates were intended to benefit health care payers, plan members, and/or the general public;

e. Whether the rebates saved health care payers, plan members, and the general public money;

f. Whether Levemir and Novolog's "preferred" formulary status reflected the drug's safety, efficacy, or cost-effectiveness, as determined by the PBMs' P&T Committees;

g. Whether Levemir and Novolog would have been placed in a "preferred" formulary position absent the rebates; and

h. The extent to which the rebating scheme would force plan members to incur additional expenses for their Levemir and Novolog prescriptions.

159. Novo Nordisk alone could not have accomplished the purpose of the Levemir/Novolog Pricing Enterprise, without the assistance of the PBMs. For Novo Nordisk to profit from the scheme, the PBMs needed to convince health care payers and plan sponsors to select their formulary, on which Levemir and Novolog were given favorable treatment. And the

PBMs did so through misrepresentations: they told clients, potential clients, and investors that they secured significant discounts. However, these discounts were only significant because the benchmark prices were artificially inflated. The discounts were fictitious: the result of a deliberate scheme to create large rebates without lowering real prices. Without these misrepresentations, the Levemir/Novolog Pricing Enterprise could not have achieved its common purpose.

160. The Levemir/Novolog Pricing Enterprise engaged in and affected interstate commerce because, *inter alia*, it set the price of drugs that were sold to and utilized by thousands of class members throughout the United States, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

161. The impacts of the Levemir/Novolog Pricing Enterprise's scheme are still in place—*i.e.*, the increased spread between the Levemir and Novolog benchmark prices and the actual prices of Levemir and Novolog is still being maintained, and increased. Consequently, PBMs and pharmacies make a profit on the spread between benchmark price and the actual acquisition cost—*i.e.*, the rebates. Under this system, a higher spread results in increased profits to PBMs and pharmacies.

162. The foregoing evidenced that Novo Nordisk, CVS Caremark, Express Scripts, and OptumRx were each willing participants in the Levemir/Novolog Pricing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose, *i.e.*, through Novo Nordisk's artificial inflation of the Levemir and Novolog benchmark prices, coupled with Novo Nordisk's and the PBMs' creation of substantial rebates, and the PBMs' misstatements to the drug-purchasing public that those rebates benefitted health care payer and consumers like Plaintiffs and the class.

B. Conduct of the Levemir/Novolog Pricing Enterprise

163. During the class period, Novo Nordisk exerted control over the Levemir/Novolog Pricing Enterprise and participated in the operation or management of the affairs of the Levemir/Novolog Pricing Enterprise, directly or indirectly, in the following ways:

a. Novo Nordisk selected and published the Levemir and Novolog benchmark prices;

b. Novo Nordisk periodically raised the published Levemir and Novolog benchmark prices;[63]

c. Novo Nordisk granted to the PBMs substantial rebates representing discounts off of the Levemir and Novolog benchmark prices in exchange for the PBMs' promise to give Levemir and Novolog exclusive or at least favorable, formulary placement;

d. Novo Nordisk concealed from the public the amount and purpose of the rebates;

e. Novo Nordisk intended that the PBMs would (and did) distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Levemir and Novolog) saved health care payers and consumers like Plaintiffs and class members money on their prescription needs; and

f. Representing to the general public, through stating of Levemir and Novolog's benchmark prices without stating that the benchmark prices differed substantially from that negotiated by the PBMs, that the Levemir and Novolog benchmark prices reflected or approximated Levemir and Novolog's actual costs.

164. The scheme had a hierarchical decision-making structure that was headed by Novo Nordisk. Novo Nordisk controlled the Levemir and Novolog benchmark prices, and doled out rebates to the PBMs in exchange for the PBMs' assurances that Levemir and Novolog would receive exclusive, or at least favorable, formulary placement.

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[63] *See, e.g.*, *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 172 (D. Mass. 2003) (finding sufficient allegations of defendants' participation in the conduct of an association-in-fact enterprise where the defendants "collectively determined the price that [the enterprise] would charge doctors for [a drug]," and "set the published AWP thereby determining the spread").

165. The PBMs also participated in the conduct of the affairs of the Levemir/Novolog Pricing Enterprise, directly or indirectly, in the following ways:

a. The PBMs promised to, and did, confer on Levemir and Novolog exclusive or at least favorable formulary placement;

b. The PBMs distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Levemir and Novolog) saved health care payers and consumers like Plaintiffs and class members money on their prescription needs; and

c. The PBMs concealed the existence or amount of the rebates—including those given to their competitors—to further the fraudulent pricing scheme.

166. The scheme devised and implemented by Novo Nordisk, as well as other members of the Levemir/Novolog Pricing Enterprise, amounted to a common course of conduct intended to (a) secure favorable formulary positioning for Levemir and Novolog; (b) entice health care payers to select one of the PBMs' formularies; and thereby (c) secure payment for prescriptions of Levemir and Novolog written by plan members' physicians.

C. Novo Nordisk's Pattern of Racketeering Activity

167. Novo Nordisk conducted and participated in the conduct of the affairs of the Levemir/Novolog Pricing Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The pattern of racketeering activity by the Levemir/Novolog Pricing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Levemir and Novolog pricing scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), through which Novo Nordisk and the PBMs intended to defraud Plaintiffs, members of the class, and other intended victims.

168. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and members of the class. Novo Nordisk and the PBMs calculated and intentionally crafted the Levemir and Novolog pricing scheme to ensure their own profits remained high, without regard to the effect such pricing behavior had on Plaintiffs and members of the class who would be over-billed for Levemir and Novolog. In designing and implementing the scheme, at all times Novo Nordisk was cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the pharmaceutical companies and PBMs in setting benchmark prices and establishing rebates.

169. By intentionally and artificially inflating the Levemir and Novolog benchmark prices, and then subsequently failing to disclose such practices to the individual patients, health plans, and insurers, Novo Nordisk and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

170. Novo Nordisk's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs and members of the class. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Novo Nordisk was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the class. Novo Nordisk has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Levemir/Novolog Pricing Enterprise.

171. The pattern of racketeering activity alleged herein and the Levemir/Novolog Pricing Enterprise are separate and distinct from each other. Likewise, Novo Nordisk is distinct from the Levemir/Novolog Pricing Enterprise.

172. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

D. Novo Nordisk's Use of the U.S. Mail and Interstate Wire Facilities

173. The Levemir/Novolog Pricing Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the transmission and publication of false and misleading information concerning the Levemir and Novolog benchmark prices; the payment from Novo Nordisk to the PBMs of substantial rebates off of the benchmark price; and transmission of false or incomplete statements intended to mislead health care payers and consumers regarding the existence, amount, and purpose of the rebates.

174. During the class period, the Levemir/Novolog Pricing Enterprise's unlawful conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents, information, products, and funds by the U.S. Mail and interstate wire facilities.

175. The nature and pervasiveness of the Levemir and Novolog pricing fraud scheme, which was orchestrated out of the corporate headquarters of Novo Nordisk and each PBM, necessarily required those headquarters to communicate directly and frequently by U.S. Mail and interstate wire facilities.

176. Many of the precise dates of the Levemir/Novolog Pricing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding RICO predicate acts of mail and

wire fraud) have been hidden and cannot be alleged without access to Novo Nordisk's, CVS Caremark's, Express Scripts's, and OptumRx's books and records. Indeed, an essential part of the successful operation of the Enterprise alleged herein depended upon secrecy. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the scheme; Plaintiffs describe this below.

177. Novo Nordisk's use of the U.S. Mail and interstate wire facilities to perpetrate the Levemir and Novolog pricing fraud scheme involved thousands of communications throughout the class period including, *inter alia*:

a. Marketing materials about Novo Nordisk's Levemir and Novolog products and its price, which Novo Nordisk sent to health care payers and health care providers located across the country;

b. Written communications between Novo Nordisk and the publishers of benchmark price compendia regarding the Levemir and Novolog benchmark prices and their subsequent mark-ups, which occurred on a regular basis each year;

c. Written representations and telephone calls between Novo Nordisk and CVS Caremark regarding Levemir and Novolog markups and benchmark prices;

d. Written representations and telephone calls between Novo Nordisk and Express Scripts regarding Levemir and Novolog markups and benchmark prices;

e. Written representations and telephone calls between Novo Nordisk and OptumRx regarding Levemir and Novolog markups and benchmark prices;

f. Written representations and telephone calls between Novo Nordisk and CVS Caremark regarding Levemir and Novolog rebates;

g. Written representations and telephone calls between Novo Nordisk and Express Scripts regarding Levemir and Novolog rebates;

h. Written representations and telephone calls between Novo Nordisk and OptumRx regarding Levemir and Novolog rebates;

i. Hundreds of e-mails between Novo Nordisk and the PBMs agreeing to or effectuating the implementation of the Levemir and Novolog pricing fraud scheme;

j. Written and oral communications directed to U.S. Government agencies and private insurers that fraudulently misrepresented what the Levemir and Novolog benchmark prices were; the existence, amount, or purpose of the Levemir and Novolog rebates; and the true costs of Levemir and Novolog that were designed to conceal the scheme, deter investigations into Levemir and Novolog pricing, or forestall changes to healthcare payers reimbursement of Levemir and Novolog prescriptions based on something other than Levemir and Novolog benchmark prices; and

k. receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

178. In addition to the above-referenced RICO predicate acts, it was foreseeable to Novo Nordisk that the PBMs would distribute publications through the U.S. Mail and by interstate wire facilities, and in those publications, claim that the increased rebates would benefit third-party payors and consumers like Plaintiffs and class members.

E. Damages Caused by Novo Nordisk's Levemir and Novolog Pricing Fraud

179. Novo Nordisk's violations of federal law and its pattern of racketeering activity have directly and proximately caused Plaintiffs and class members to be injured in their business or property because Plaintiffs and class members have paid inflated out-of-pocket expenses for Levemir and/or Novolog.

180. As described above, when a healthcare consumer fills a prescription for a drug like Levemir and/or Novolog, she is responsible for paying all or a portion of the medication's cost. If the consumer is uninsured, she is responsible for 100% of the drug's costs. If the consumer has a high-deductible health plan, she must pay for 100% of her drugs until she satisfies her deductible. If the consumer's health plan contains a coinsurance requirement, she is responsible for paying a percentage of her drug's cost. And if the consumer is a member of a Medicare Part D plan, her plan's contributions to the cost of her drugs cuts out after a certain

threshold is reached, saddling the consumer with a high percentage of her drug costs until she reaches her maximum contribution.

181. The amount of each of these cash payments is based on the drug's benchmark price. Therefore, when Novo Nordisk, through the Levemir/Novolog Pricing Enterprise, artificially inflates the Levemir and Novolog benchmark prices, it also artificially inflates the consumers' out-of-pocket expenses.

182. Plaintiffs' injuries, and those of the class members, were proximately caused by Novo Nordisk's racketeering activity. But for the misstatements made by Novo Nordisk and the PBMs and the pricing scheme employed by the Levemir/Novolog Pricing Enterprise, Plaintiffs and others similarly situated would have paid less for their out-of-pocket Levemir and Novolog expenses.

183. Plaintiffs' injuries were directly caused by Novo Nordisk's racketeering activity. Drug wholesalers, health care payers, and others in the pharmaceutical supply chain are not responsible for cash payments (by those who have no insurance), coinsurance or deductible payments (by private and public plan members), and payments made in the "Donut Hole" (for Medicare members). So, although the misstatements made by the PBMs in furtherance of the Levemir/Novolog Pricing Enterprise were directed primarily to health care payers, those payers did not have to make cash payments for the portions of prescription drugs costs that were, by definition, excluded from their responsibility. Therefore, the health care payers did not suffer the overcharges that are the harms alleged in this suit.

184. And although the Levemir/Novolog Pricing Enterprise was effectuated to give Novo Nordisk a wrongfully-obtained advantage over its competitors, the harm this suit seeks to remedy was not suffered by Novo Nordisk's competitors.

185. Plaintiffs and those similarly situated were most directly harmed by the fraud, and there are no other Plaintiffs or class of plaintiffs better situated to seek a remedy for the economic harms to consumers from Novo Nordisk's fraudulent scheme.

186. By virtue of these violations of 18 U.S.C. § 1962(c), Novo Nordisk is liable to Plaintiffs for three times the damages they have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT TWO: Violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* against Eli Lilly

187. Plaintiffs repeat and incorporate by reference all preceding and succeeding paragraphs and allegations.

188. This claim is brought on behalf of the class against Eli Lilly for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1962 *et seq.*

189. Defendant is a "person" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

190. Plaintiffs and the members of the class are each "persons," as that term is defined in 18 U.S.C. § 1961(3) who were injured in their business or property as a result of Eli Lilly's wrongful conduct.

A. The Humalog Pricing Enterprise

191. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.

192. Eli Lilly formed just such an association-in-fact enterprise—sometimes referred to in this complaint as the Humalog Pricing Enterprise. The Humalog Pricing Enterprise consists of (a) Eli Lilly, including its employees and agents; (b) the PBM CVS Caremark, including its employees and agents; (c) the PBM Express Scripts, including its employees and agents; and (d) the PBM OptumRx, including its employees and agents.

193. The Humalog Pricing Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to secure an exclusive, or at least favorable, formulary position for Eli Lilly's long-acting analog insulin product, Humalog, as a treatment for type 1 and 2 diabetes to the exclusion or detriment of competitor products and consumers.

194. To accomplish this purpose, the Humalog Pricing Enterprise periodically and systematically inflated the benchmark price of Humalog and represented—either affirmatively or through half-truths and omissions—to the general public, health care payers, and consumers, including Plaintiffs and the class, that Humalog' benchmark price fairly and accurately reflected the actual cost of this drug. The Enterprise concealed from the public, health care payers, and consumers, like Plaintiffs and class members, the existence and amount of steep rebates Eli Lilly gave to the PBMs. These rebates were worth at least 25% of the benchmark price. The Humalog Pricing Enterprise also concealed from the public the purpose of these rebates: The difference between the benchmark price and the real price of Humalog negotiated by the PBMs resulted in increased profits for the PBMs. These large rebates served to ensure that the PBMs would place, and maintain, Humalog in a preferred or favorable position on the PBMs' formularies. By securing a favorable position on the formulary, the Humalog Pricing Enterprise

ensured that a larger number of Humalog prescriptions would be written and filled. This scheme translated into higher sales (and therefore profits) for Eli Lilly and larger spreads for the PBMs.

195. The persons engaged in the Humalog Pricing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Eli Lilly. There is regular communication between Eli Lilly and each of the PBMs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Eli Lilly and the PBMs share information regarding the Humalog benchmark price and discuss and agree on rebate amounts. Eli Lilly and the PBMs functioned as a continuing unit for the purposes of implementing the Humalog pricing scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

196. At all relevant times, CVS Caremark was aware of Eli Lilly's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. CVS Caremark struck rebate deals with Eli Lilly to conceal the true price of Humalog and profit from the inflated rebates. CVS Caremark represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the cost of Humalog for consumers, because the published benchmark price was falsely inflated. CVS Caremark also knew, but did not disclose, that the other PBMs—Express Scripts and OptumRx—were engaged in the same rebating scheme, to the detriment of consumers. But for the Humalog Pricing Enterprise's unlawful fraud, CVS Caremark would have had the incentive to disclose the deceit by Eli Lilly, thereby forcing competition on real price. By failing to

disclose this information, CVS Caremark perpetuated the Humalog Pricing Enterprise's scheme, and reaped substantial profits.

197. At all relevant times, Express Scripts was aware of Eli Lilly's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. Express Scripts struck rebate deals with Eli Lilly to conceal the true price of Humalog and profit from the inflated rebates. Express Scripts represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the cost of Humalog for consumers, because the published benchmark price was falsely inflated. Express Scripts also knew, but did not disclose, that the other PBMs—CVS Caremark and OptumRx—were engaged in the same rebating scheme, to the detriment of consumers. But for the Humalog Pricing Enterprise's unlawful fraud, Express Scripts would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, Express Scripts perpetuated the Humalog Pricing Enterprise's scheme, and reaped substantial profits.

198. At all relevant times, OptumRx was aware of Eli Lilly's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. OptumRx struck rebate deals with Eli Lilly to conceal the true price of Humalog and profit from the inflated rebates. OptumRx represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the cost of Humalog for consumers, because the published benchmark price was falsely inflated. OptumRx also knew, but did not disclose, that the other PBMs—CVS Caremark and Express Scripts—were engaged

in the same rebating scheme, to the detriment of consumers. But for the Humalog Pricing Enterprise's unlawful fraud, OptumRx would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, OptumRx perpetuated the Humalog Pricing Enterprise's scheme, and reaped substantial profits.

199. Furthermore, as public scrutiny, media coverage, and congressional investigations have focused on the rapidly-inflating prices of lifesaving drugs—including insulin—the PBMs did not challenge Eli Lilly's reported benchmark prices, terminate their role in the Humalog Pricing Enterprise, nor disclose publicly that the Humalog benchmark price did not accurately reflect the price actually paid for the drug.

200. CVS Caremark, Express Scripts, and OptumRx participated in the conduct of the Humalog Pricing Enterprise, sharing the common purpose of securing exclusive or favorable formulary position for Humalog, through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and (5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343. The PBMs knowingly made material misstatements to health care payers, plan members, and the general public in furtherance of the fraudulent scheme regarding:

a. The actual price of Humalog;

b. The extent to which the actual price of Humalog departed from the published, artificially-inflated benchmark price;

c. The extent to which Eli Lilly and the PBMs had negotiated the rebates discounting the benchmark price of Humalog in good faith and for a proper purpose;

d. Whether the rebates were intended to benefit health care payers, plan members, and/or the general public;

e. Whether the rebates saved health care payers, plan members, and the general public money;

f. Whether Humalog's "preferred" formulary status reflected the drug's safety, efficacy, or cost-effectiveness, as determined by the PBMs' P&T Committees;

g. Whether Humalog would have been placed in a "preferred" formulary position absent the rebates; and

h. The extent to which the rebating scheme would force plan members to incur additional expenses for their Humalog prescriptions.

201. Eli Lilly alone could not have accomplished the purpose of the Humalog Pricing Enterprise, without the assistance of the PBMs. For Eli Lilly to profit from the scheme, the PBMs needed to convince health care payers and plan sponsors to select their formulary, on which Humalog was given favorable treatment. And the PBMs did so through misrepresentations: they told clients, potential clients, and investors that they secured significant discounts. However, these discounts were only significant because the benchmark prices were artificially inflated. The discounts were fictitious: the result of a deliberate scheme to create large rebates without lowering real prices. Without these misrepresentations, the Humalog Pricing Enterprise could not have achieved its common purpose.

202. The Humalog Pricing Enterprise engaged in and affected interstate commerce because, *inter alia*, it set the price of drugs that were sold to and utilized by thousands of class members throughout the United States, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

203. The impacts of the Humalog Pricing Enterprise's scheme are still in place—*i.e.*, the increased spread between the Humalog benchmark price and the actual price of Humalog is still being maintained, and increased. Consequently, PBMs and pharmacies make a profit on the spread between benchmark price and the actual acquisition cost—*i.e.*, the rebates. Under this system, a higher spread results in increased profits to PBMs and pharmacies.

204. The foregoing evidenced that Eli Lilly, CVS Caremark, Express Scripts, and OptumRx were each willing participants in the Humalog Pricing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose, *i.e.*, through Eli Lilly's artificial inflation of the Humalog benchmark price, coupled with Eli Lilly's and the PBMs' creation of substantial rebates, and the PBMs' misstatements to the drug-purchasing public that those rebates benefitted health care payer and consumers like Plaintiffs and the class.

B. Conduct of the Humalog Pricing Enterprise

205. During the class period, Eli Lilly exerted control over the Humalog Pricing Enterprise and participated in the operation or management of the affairs of the Humalog Pricing Enterprise, directly or indirectly, in the following ways:

a. Eli Lilly selected and published the Humalog benchmark price;

b. Eli Lilly periodically raised the published Humalog benchmark price;[64]

c. Eli Lilly granted to the PBMs substantial rebates representing discounts off of the Humalog benchmark price in exchange for the PBMs' promise to give Humalog exclusive or at least favorable, formulary placement;

d. Eli Lilly concealed from the public the amount and purpose of the rebates;

e. Eli Lilly intended that the PBMs would (and did) distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Humalog) saved health care payers and consumers like Plaintiffs and class members money on their prescription needs; and

f. Representing to the general public, through stating of Humalog's benchmark price without stating that the benchmark price differed substantially from that negotiated by PBMs, that the Humalog benchmark price reflected or approximated Humalog's actual cost.

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[64] *See, e.g.*, *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 172 (D. Mass. 2003) (finding sufficient allegations of defendants' participation in the conduct of an association-in-fact enterprise where the defendants "collectively determined the price that [the enterprise] would charge doctors for [a drug]," and "set the published AWP thereby determining the spread").

206. The scheme had a hierarchical decision-making structure that was headed by Eli Lilly. Eli Lilly controlled the Humalog benchmark price, and doled out rebates to the PBMs in exchange for the PBMs' assurances that Humalog would receive exclusive, or at least favorable, formulary placement.

207. The PBMs also participated in the conduct of the affairs of the Humalog Pricing Enterprise, directly or indirectly, in the following ways:

a. The PBMs promised to, and did, confer on Humalog exclusive or at least favorable formulary placement;

b. The PBMs distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Humalog) saved health care payers and consumers like Plaintiffs and class members money on their prescription needs; and

c. The PBMs concealed the existence or amount of the rebates—including those given to their competitors—to further the fraudulent pricing scheme.

208. The scheme devised and implemented by Eli Lilly, as well as other members of the Humalog Pricing Enterprise, amounted to a common course of conduct intended to (a) secure favorable formulary positioning for Humalog; (b) entice health care payers to select one of the PBMs' formularies; and thereby (c) secure payment for prescriptions of Humalog written by plan members' physicians.

C. Eli Lilly's Pattern of Racketeering Activity

209. Eli Lilly conducted and participated in the conduct of the affairs of the Humalog Pricing Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The pattern of racketeering activity by the Humalog pricing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Humalog pricing scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B).

Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), through which Eli Lilly and the PBMs intended to defraud Plaintiffs, members of the class, and other intended victims.

210. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and members of the class. Eli Lilly and the PBMs calculated and intentionally crafted the Humalog pricing scheme to ensure their own profits remained high, without regard to the effect such pricing behavior had on Plaintiffs and members of the class who would be over-billed for Humalog. In designing and implementing the scheme, at all times Eli Lilly was cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the pharmaceutical companies and PBMs in setting benchmark prices and establishing rebates.

211. By intentionally and artificially inflating the Humalog benchmark price, and then subsequently failing to disclose such practices to the individual patients, health plans, and insurers, Eli Lilly and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

212. Eli Lilly's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs and members of the class. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Eli Lilly was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the class. Eli Lilly has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Humalog Pricing Enterprise.

213. The pattern of racketeering activity alleged herein and the Humalog Pricing Enterprise are separate and distinct from each other. Likewise, Eli Lilly is distinct from the Humalog Pricing Enterprise.

214. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

D. Eli Lilly's Use of the U.S. Mail and Interstate Wire Facilities

215. The Humalog Pricing Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the transmission and publication of false and misleading information concerning the Humalog benchmark price; the payment from Eli Lilly to the PBMs of substantial rebates off of the benchmark price; and transmission of false or incomplete statements intended to mislead health care payers and consumers regarding the existence, amount, and purpose of the rebates.

216. During the class period, the Humalog Pricing Enterprise's unlawful conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents, information, products, and funds by the U.S. Mail and interstate wire facilities.

217. The nature and pervasiveness of the Humalog pricing fraud scheme, which was orchestrated out of the corporate headquarters of Eli Lilly and each PBM, necessarily required those headquarters to communicate directly and frequently by U.S. Mail and interstate wire facilities.

218. Many of the precise dates of the Humalog Pricing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Eli Lilly's, CVS

Caremark's, Express Scripts's, and OptumRx's books and records. Indeed, an essential part of the successful operation of the Enterprise alleged herein depended upon secrecy. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the Scheme; Plaintiffs describe this below.

219. Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the Humalog pricing fraud scheme involved thousands of communications throughout the class period including, *inter alia*:

a. Marketing materials about Eli Lilly's Humalog product and its price, which Eli Lilly sent to health care payers and health care providers located across the country;

b. Written communications between Eli Lilly and the publishers of benchmark price compendia regarding the Humalog benchmark price and its subsequent mark-ups, which occurred on a regular basis each year;

c. Written representations and telephone calls between Eli Lilly and CVS Caremark regarding Humalog markups and benchmark price;

d. Written representations and telephone calls between Eli Lilly and Express Scripts regarding Humalog markups and benchmark price;

e. Written representations and telephone calls between Eli Lilly and OptumRx regarding Humalog markups and benchmark price;

f. Written representations and telephone calls between Eli Lilly and CVS Caremark regarding Humalog rebates;

g. Written representations and telephone calls between Eli Lilly and Express Scripts regarding Humalog rebates;

h. Written representations and telephone calls between Eli Lilly and OptumRx regarding Humalog rebates;

i. Hundreds of e-mails between Eli Lilly and the PBMs agreeing to or effectuating the implementation of the Humalog pricing fraud scheme;

j. Written and oral communications directed to U.S. Government agencies and private insurers that fraudulently misrepresented what the Humalog benchmark price was; the existence, amount, or purpose of the Humalog rebates; and the true cost of Humalog that were designed to conceal the scheme, deter investigations into Humalog pricing, or forestall changes to healthcare payers reimbursement of Humalog prescriptions based on something other than Humalog benchmark price; and

k. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme; and

220. In addition to the above-referenced RICO predicate acts, it was foreseeable to Eli Lilly that the PBMs would distribute publications through the U.S. Mail and by interstate wire facilities, and in those publications, claim that the increased rebates would benefit third-party payors and consumers like Plaintiffs and class members.

E. Damages Caused by Eli Lilly's Humalog Pricing Fraud

221. Eli Lilly's violations of federal law and its pattern of racketeering activity have directly and proximately caused Plaintiffs and the class members to be injured in their business or property because Plaintiffs and class members have paid inflated out-of-pocket expenses for Humalog.

222. As described above, when a healthcare consumer fills a prescription for a drug like Humalog, she is responsible for paying all or a portion of the medication's cost. If the consumer is uninsured, she is responsible for 100% of the drug's costs. If the consumer has a high-deductible health plan, she must pay for 100% of her drugs until she satisfies her deductible. If the consumer's health plan contains a coinsurance requirement, she is responsible for paying a percentage of her drug's cost. And if the consumer is a member of a Medicare Part D plan, her plan's contributions to the cost of her drugs cuts out after a certain threshold is reached, saddling the consumer with a high percentage of her drug costs until she reaches her maximum contribution.

223. The amount of each of these cash payments is based on the drug's benchmark price. Therefore, when Eli Lilly, through the Humalog Pricing Enterprise, artificially inflates the Humalog benchmark price, it also artificially inflates the consumers' out-of-pocket expenses.

224. Plaintiffs' injuries, and those of the class members, were proximately caused by Eli Lilly's racketeering activity. But for the misstatements made by Eli Lilly and the PBMs, and the pricing scheme employed by the Humalog Pricing Enterprise, Plaintiffs and others similarly situated would have paid less for their out-of-pocket Humalog expenses.

225. Plaintiffs' injuries were directly caused by Eli Lilly's racketeering activity. Drug wholesalers, health care payers, and others in the pharmaceutical supply chain are not responsible for cash payments (by those who have no insurance), coinsurance or deductible payments (by private and public plan members), and payments made in the "Donut Hole" (for Medicare members). So, although the misstatements made by the PBMs in furtherance of the Humalog Pricing Enterprise were directed primarily to health care payers, those payers did not have to make cash payments for the portions of prescription drugs costs that were, by definition, excluded from their responsibility. Therefore, the health care payers did not suffer the overcharges that are the harms alleged in this suit.

226. And although the Humalog Pricing Enterprise was effectuated to give Eli Lilly a wrongfully-obtained advantage over its competitors, the harm this suit seeks to remedy was not suffered by Eli Lilly's competitors.

227. Plaintiffs and those similarly situated were most directly harmed by the fraud, and there are no other plaintiffs or class of plaintiffs better situated to seek a remedy for the economic harms to consumers from Eli Lilly's fraudulent scheme.

228. By virtue of these violations of 18 U.S.C. § 1962(c), Eli Lilly is liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT THREE: Violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.* against Sanofi

229. Plaintiffs repeat and incorporate by reference all preceding and succeeding paragraphs and allegations.

230. This claim is brought on behalf of the class against Sanofi for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1962 *et seq.*

231. Defendant is a "person" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

232. Plaintiffs and the members of the class are each "persons," as that term is defined in 18 U.S.C. § 1961(3) who were injured in their business or property as a result of Sanofi's wrongful conduct.

A. The Lantus Pricing Enterprise

233. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose.

234. Sanofi formed just such an association-in-fact enterprise—sometimes referred to in this complaint as the Lantus Pricing Enterprise. The Lantus Pricing Enterprise consists of (a) Sanofi, including its employees and agents; (b) the PBM CVS Caremark, including its employees and agents; (c) the PBM Express Scripts, including its employees and agents; and (d) the PBM OptumRx, including its employees and agents.

235. The Lantus Pricing Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to secure an exclusive, or at least favorable,

formulary position for Sanofi's long-acting analog insulin product, Lantus, as a treatment for type 1 and 2 diabetes to the exclusion or detriment of competitor products and consumers.

236. To accomplish this purpose, the Lantus Pricing Enterprise periodically and systematically inflated the benchmark price of Lantus and represented—either affirmatively or through half-truths and omissions—to the general public, health care payers, and consumers, including Plaintiffs and the class, that Lantus' benchmark price fairly and accurately reflected the actual cost of this drug. The Lantus Pricing Enterprise concealed from the public, health care payers, and consumers, like Plaintiffs and the class members, the existence and amount of steep rebates Sanofi gave to the PBMs. These rebates were worth at least 25% of the benchmark price. The Lantus Pricing Enterprise also concealed from the public the purpose of these rebates: The difference between the benchmark price and the real price of Lantus negotiated by the PBMs resulted in increased profits for the PBMs. These large rebates served to ensure that the PBMs would place, and maintain, Lantus in a preferred or favorable position on the PBMs' formularies. By securing a favorable position on the formulary, the Lantus Pricing Enterprise ensured that a larger number of Lantus prescriptions would be written and filled. This scheme translated into higher sales (and therefore profits) for Sanofi and larger spreads for the PBMs.

237. The persons engaged in the Lantus Pricing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Sanofi. There is regular communication between Sanofi and each of the PBMs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Sanofi and the PBMs share information regarding the Lantus benchmark price and discuss and agree on rebate amounts. Sanofi and the PBMs functioned as a continuing unit for the purposes of implementing the Lantus pricing

scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

238. At all relevant times, CVS Caremark was aware of Sanofi's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. CVS Caremark struck rebate deals with Sanofi to conceal the true price of Lantus and profit from the inflated rebates. CVS Caremark represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the cost of Lantus for consumers, because the published benchmark price was falsely inflated. CVS Caremark also knew, but did not disclose, that the other PBMs—Express Scripts and OptumRx—were engaged in the same rebating scheme, to the detriment of consumers. But for the Lantus Pricing Enterprise's unlawful fraud, CVS Caremark would have had the incentive to disclose the deceit by Sanofi, thereby forcing competition on real price. By failing to disclose this information, CVS Caremark perpetuated the Lantus Pricing Enterprise's scheme, and reaped substantial profits.

239. At all relevant times, Express Scripts was aware of Sanofi's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. Express Scripts struck rebate deals with Sanofi to conceal the true price of Lantus and profit from the inflated rebates. Express Scripts represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the cost of Lantus for consumers, because the published benchmark price was falsely inflated. Express Scripts also knew, but did not disclose, that the other PBMs—CVS Caremark and OptumRx—

were engaged in the same rebating scheme, to the detriment of consumers. But for the Lantus Pricing Enterprise's unlawful fraud, Express Scripts would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, Express Scripts perpetuated the Lantus Pricing Enterprise's scheme, and reaped substantial profits.

240. At all relevant times, OptumRx was aware of Sanofi's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct. OptumRx struck rebate deals with Sanofi to conceal the true price of Lantus and profit from the inflated rebates. OptumRx represented to the public that the rebates it negotiated saved health care payers and their plan members (including Plaintiffs and members of the class) money on their prescription needs. But it knew that the rebates did not actually decrease the cost of Lantus for consumers, because the published benchmark price was falsely inflated. OptumRx also knew, but did not disclose, that the other PBMs—CVS Caremark and Express Scripts—were engaged in the same rebating scheme, to the detriment of consumers. But for the Lantus Pricing Enterprise's unlawful fraud, OptumRx would have been incentivized to disclose the deceit by its competitors, thereby obtaining a competitive advantage. By failing to disclose this information, OptumRx perpetuated the Lantus Pricing Enterprise's scheme, and reaped substantial profits.

241. Furthermore, as public scrutiny, media coverage, and congressional investigations have focused on the rapidly-inflating prices of lifesaving drugs—including insulin—the PBMs did not challenge Sanofi's reported benchmark prices, terminate their role in the Lantus Pricing Enterprise, nor disclose publicly that the Lantus benchmark price did not accurately reflect the price actually paid for the drug.

242. CVS Caremark, Express Scripts, and OptumRx participated in the conduct of the Lantus Pricing Enterprise, sharing the common purpose of securing exclusive or favorable formulary position for Lantus, through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and (5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343. The PBMs knowingly made material misstatements to health care payers, plan members, and the general public in furtherance of the fraudulent scheme regarding:

a. The actual price of Lantus;

b. The extent to which the actual price of Lantus departed from the published, artificially-inflated benchmark price;

c. The extent to which Sanofi and the PBMs had negotiated the rebates discounting the benchmark price of Lantus in good faith and for a proper purpose;

d. Whether the rebates were intended to benefit health care payers, plan members, and/or the general public;

e. Whether the rebates saved health care payers, plan members, and the general public money;

f. Whether Lantus' "preferred" formulary status reflected the drug's safety, efficacy, or cost-effectiveness, as determined by the PBMs' P&T Committees;

g. Whether Lantus would have been placed in a "preferred" formulary position absent the rebates; and

h. The extent to which the rebating scheme would force plan members to incur additional expenses for their Lantus prescriptions.

243. Sanofi alone could not have accomplished the purpose of the Lantus Pricing Enterprise, without the assistance of the PBMs. For Sanofi to profit from the scheme, the PBMs needed to convince health care payers and plan sponsors to select their formulary, on which Lantus was given favorable treatment. And the PBMs did so through misrepresentations: they told clients, potential clients, and investors that they secured significant discounts. However, these discounts were only significant because the benchmark prices were artificially inflated.

The discounts were fictitious: the result of a deliberate scheme to create large rebates without lowering real prices. Without these misrepresentations, the Lantus Pricing Enterprise could not have achieved its common purpose.

244. The Lantus Pricing Enterprise engaged in and affected interstate commerce because, *inter alia*, it set the price of drugs that were sold to and utilized by thousands of class members throughout the United States, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

245. The impacts of the Lantus Pricing Enterprise's scheme are still in place—*i.e.*, the increased spread between the Lantus benchmark price and the actual price of Lantus is still being maintained, and increased. Consequently, PBMs and pharmacies make a profit on the spread between benchmark price and the actual acquisition cost—*i.e.*, the rebates. Under this system, a higher spread results in increased profits to PBMs and pharmacies.

246. The foregoing evidenced that Sanofi, CVS Caremark, Express Scripts, and OptumRx were each willing participants in the Lantus Pricing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose, *i.e.*, through Sanofi's artificial inflation of the Lantus benchmark price, coupled with Sanofi's and the PBMs' creation of substantial rebates, and the PBMs' misstatements to the drug-purchasing public that those rebates benefitted health care payer and consumers like Plaintiffs and the class.

B. Conduct of the Lantus Pricing Enterprise

247. During the class period, Sanofi exerted control over the Lantus Pricing Enterprise and participated in the operation or management of the affairs of the Lantus Pricing Enterprise, directly or indirectly, in the following ways:

a. Sanofi selected and published the Lantus benchmark price;

b. Sanofi periodically raised the published Lantus benchmark price;[65]

c. Sanofi granted to the PBMs substantial rebates representing discounts off of the Lantus benchmark price in exchange for the PBMs' promise to give Lantus exclusive or at least favorable, formulary placement;

d. Sanofi concealed from the public the amount and purpose of the rebates;

e. Sanofi intended that the PBMs would (and did) distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Lantus) saved health care payers and consumers like Plaintiffs and class members money on their prescription needs; and

f. The public, through stating of Lantus' benchmark price without stating that the benchmark price differed substantially from that negotiated by PBMs, that the Lantus benchmark price reflected or approximated Lantus' actual cost.

248. The scheme had a hierarchical decision-making structure that was headed by Sanofi. Sanofi controlled the Lantus benchmark price, and doled out rebates to the PBMs in exchange for the PBMs' assurances that Lantus would receive exclusive, or at least favorable, formulary placement.

249. The PBMs also participated in the conduct of the affairs of the Lantus Pricing Enterprise, directly or indirectly, in the following ways:

a. The PBMs promised to, and did, confer on Lantus exclusive or at least favorable formulary placement;

b. The PBMs distribute through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that rebates (such as those applied to Lantus) saved health care payers and consumers like Plaintiffs and class members money on their prescription needs; and

c. The PBMs concealed the existence or amount of the rebates—including those given to their competitors—to further the fraudulent pricing scheme.

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[65] *See*, *e.g.*, *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 172 (D. Mass. 2003) (finding sufficient allegations of defendants' participation in the conduct of an association-in-fact enterprise where the defendants "collectively determined the price that [the enterprise] would charge doctors for [a drug]," and "set the published AWP thereby determining the spread").

250. The scheme devised and implemented by Sanofi, as well as other members of the Lantus Pricing Enterprise, amounted to a common course of conduct intended to (a) secure favorable formulary positioning for Lantus; (b) entice health care payers to select one of the PBMs' formularies; and thereby (c) secure payment for prescriptions of Lantus written by plan members' physicians.

C. Sanofi's Pattern of Racketeering Activity

251. Sanofi conducted and participated in the conduct of the affairs of the Lantus Pricing Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The pattern of racketeering activity by the Lantus Pricing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Lantus pricing scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), through which Sanofi and the PBMs intended to defraud Plaintiffs, members of the class, and other intended victims.

252. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and members of the class. Sanofi and the PBMs calculated and intentionally crafted the Lantus pricing scheme to ensure their own profits remained high, without regard to the effect such pricing behavior had on Plaintiffs and members of the class who would be over-billed for Lantus. In designing and implementing the scheme, at all times Sanofi was cognizant of the fact that those in the distribution chain who are not part of

the industry rely on the integrity of the pharmaceutical companies and PBMs in setting benchmark prices and establishing rebates.

253. By intentionally and artificially inflating the Lantus benchmark price, and then subsequently failing to disclose such practices to the individual patients, health plans, and insurers, Sanofi and the PBMs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

254. Sanofi's and the PBMs' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiffs and members of the class. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Sanofi was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and members of the class. Sanofi has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Lantus Pricing Enterprise.

255. The pattern of racketeering activity alleged herein and the Lantus Pricing Enterprise are separate and distinct from each other. Likewise, Sanofi is distinct from the Lantus Pricing Enterprise.

256. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

D. Sanofi's Use of the U.S. Mail and Interstate Wire Facilities

257. The Lantus Pricing Enterprise engaged in and affected interstate commerce because it engaged in the following activities across state boundaries: the transmission and publication of false and misleading information concerning the Lantus benchmark price; the payment from Sanofi to the PBMs of substantial rebates off of the benchmark price; and

transmission of false or incomplete statements intended to mislead health care payers and consumers regarding the existence, amount, and purpose of the rebates.

258. During the class period, the Lantus Pricing Enterprise's unlawful conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents, information, products, and funds by the U.S. Mail and interstate wire facilities.

259. The nature and pervasiveness of the Lantus pricing fraud scheme, which was orchestrated out of the corporate headquarters of Sanofi and each PBM, necessarily required those headquarters to communicate directly and frequently by U.S. Mail and interstate wire facilities.

260. Many of the precise dates of the Lantus Pricing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to Sanofi's, CVS Caremark's, Express Scripts's, and OptumRx's books and records. Indeed, an essential part of the successful operation of the Lantus Pricing Enterprise alleged herein depended upon secrecy. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the scheme; Plaintiffs describe this below.

261. Sanofi's use of the U.S. Mail and interstate wire facilities to perpetrate the Lantus pricing fraud scheme involved thousands of communications throughout the class period including, *inter alia*:

a. Marketing materials about Sanofi's Lantus product and its price, which Sanofi sent to health care payers and health care providers located across the country;

b. Written communications between Sanofi and the publishers of benchmark price compendia regarding the Lantus benchmark price and its subsequent mark-ups, which occurred on a regular basis each year;

c. Written representations and telephone calls between Sanofi and CVS Caremark regarding Lantus markups and benchmark price;

d. Written representations and telephone calls between Sanofi and Express Scripts regarding Lantus markups and benchmark price;

e. Written representations and telephone calls between Sanofi and OptumRx regarding Lantus markups and benchmark price;

f. Written representations and telephone calls between Sanofi and CVS Caremark regarding Lantus rebates;

g. Written representations and telephone calls between Sanofi and Express Scripts regarding Lantus rebates;

h. Written representations and telephone calls between Sanofi and OptumRx regarding Lantus rebates;

i. Hundreds of e-mails between Sanofi and the PBMs agreeing to or effectuating the implementation of the Lantus pricing fraud scheme;

j. Written and oral communications directed to U.S. Government agencies and private insurers that fraudulently misrepresented what the Lantus benchmark price was; the existence, amount, or purpose of the Lantus rebates; and the true cost of Lantus that were designed to conceal the scheme, deter investigations into Lantus pricing, or forestall changes to healthcare payers reimbursement of Lantus prescriptions based on something other than the Lantus benchmark price; and

k. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

262. In addition to the above-referenced RICO predicate acts, it was foreseeable to Sanofi that the PBMs would distribute publications through the U.S. Mail and by interstate wire facilities, and in those publications, claim that the increased rebates would benefit third-party payors and consumers like Plaintiffs and class members.

E. Damages Caused by Sanofi's Lantus Pricing Fraud

263. Sanofi's violations of federal law and its pattern of racketeering activity have directly and proximately caused Plaintiffs and the class members to be injured in their business

or property because Plaintiffs and class members have paid inflated out-of-pocket expenses for Lantus.

264. As described above, when a healthcare consumer fills a prescription for a drug like Lantus, she is responsible for paying all or a portion of the medication's cost. If the consumer is uninsured, she is responsible for 100% of the drug's costs. If the consumer has a high-deductible health plan, she must pay for 100% of her drugs until she satisfies her deductible. If the consumer's health plan contains a coinsurance requirement, she is responsible for paying a percentage of her drug's cost. And if the consumer is a member of a Medicare Part D plan, her plan's contributions to the cost of her drugs cuts out after a certain threshold is reached, saddling the consumer with a high percentage of her drug costs until she reaches her maximum contribution.

265. The amount of each of these cash payments is based on the drug's benchmark price. Therefore, when Sanofi, through the Lantus Pricing Enterprise, artificially inflates the Lantus benchmark price, it also artificially inflates the consumers' out-of-pocket expenses.

266. Plaintiffs' injuries, and those of the class members, were proximately caused by Sanofi's racketeering activity. But for the misstatements made by Sanofi and the PBMs and the pricing scheme employed by the Lantus Pricing Enterprise, Plaintiffs and others similarly situated would have paid less for their out-of-pocket Lantus expenses.

267. Plaintiffs' injuries were directly caused by Sanofi's racketeering activity. Drug wholesalers, health care payers, and others in the pharmaceutical supply chain are not responsible for cash payments (by those who have no insurance), coinsurance or deductible payments (by private and public plan members), and payments made in the "Donut Hole" (for Medicare members). So, although the misstatements made by the PBMs in furtherance of the

Lantus Pricing Enterprise were directed primarily to health care payers, those payers did not have to make cash payments for the portions of prescription drugs costs that were, by definition, excluded from their responsibility. Therefore, the health care payers did not suffer the overcharges that are the harms alleged in this suit.

268. And although the Lantus Pricing Enterprise was effectuated to give Sanofi a wrongfully-obtained advantage over its competitors, the harm this suit seeks to remedy was not suffered by Sanofi's competitors.

269. Plaintiffs and those similarly situated were most directly harmed by the fraud, and there is no other plaintiffs or class of plaintiffs better situated to seek a remedy for the economic harms to consumers from Sanofi's fraudulent scheme.

270. By virtue of these violations of 18 U.S.C. § 1962(c), Sanofi is liable to Plaintiffs for three times the damages Plaintiffs have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT FOUR: Violation of §§ 1 AND 3 of the Sherman Act, 15 U.S.C. §§ 1, 3 *et seq.* against all Defendants

271. Plaintiffs repeat and incorporate by reference all preceding and succeeding paragraphs and allegations.

272. During the class period, defendants engaged in a continuing combination or conspiracy to unreasonably restrain trade and commerce in violation of §§1 and 3 of the Sherman Act, 15 U.S.C. §§1 and 3, by engaging in a conspiracy to artificially raise list prices while maintaining and/or stabilizing the net prices for Levemir, Lantus, Novolog, and Humalog in the United States.

273. In particular, defendants have agreed, combined and conspired to raise and/or fix, the benchmark prices of Levemir, Lantus, Levemir, and Humalog in the United States.

274. In formulating and effectuating their contract, combination or conspiracy, defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which was to artificially fix and/or raise the benchmark prices of Levemir, Lantus, Levemir, and Humalog in the United States.

275. Defendants' combination or conspiracy consisted of a continuing agreement, understanding and concerted action among defendants.

276. Defendants' conspiracy had the effect of artificially inflating the benchmark prices Levemir, Lantus, Levemir, and Humalog in the United States.

277. As a direct and proximate result of defendants' unlawful conduct, plaintiffs and the other members of the Nationwide Class paid more for Levemir, Lantus, Levemir, and Humalog than they otherwise would have paid in the absence of defendants' unlawful conduct.

278. By reason of defendants' unlawful conduct, plaintiffs and members of the Nationwide Class have been deprived of free and open competition on the real prices of Levemir, Lantus, Levemir, and Humalog in the United States.

279. As a direct and proximate result of defendants' conduct, plaintiffs and members of the Nationwide Class have been injured and damaged in their property in an amount to be determined.

280. These agreements constitute trade restraints made between direct competitors that are unlawful under all three applicable standards of review: (1) the per se standard, which governs bid-rigging and the allocation of markets by horizontal agreement; (2) the "quick-look" standard, which governs apparently anticompetitive schemes with which the courts lack familiarity; and (3) the rule-of-reason standard (the "Rule of Reason"), which governs all other challenged restraints of trade. Plaintiffs respectfully submit that the Court should apply well-

recognized per se rules in order to condemn the challenged trade restraints, but in an abundance of caution pleads this claim in the alternative so that it is raised not only under the per se rules, but also under the "quick-look" standard and the Rule of Reason.

281. Plaintiffs and members of the Nationwide Class are entitled to an injunction against defendants, preventing and restraining the violations alleged herein.

COUNT FIVE: Violation of the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq.* against Sanofi

282. Plaintiffs repeat and incorporate by reference all preceding and succeeding paragraphs and allegations.

283. This claim is brought by Plaintiffs who paid for Lantus, on behalf of all members of the Class. While Plaintiffs and class members hail from across the country, Sanofi U.S. is a corporation with its headquarters in Bridgewater, New Jersey. New Jersey "has a powerful incentive to insure that local merchants deal fairly with citizens of other states and countries,"[66] and a "strong interest 'in regulating its domestic businesses and in deterring fraudulent business practices.'"[67] Furthermore, New Jersey has some of the strongest consumer protection laws in the country so, although other states may have some interest in protecting its own consumers, that interest is not frustrated by the application of New Jersey's law. "If a strong state policy or interest will [not be] frustrated by the failure to apply [that state's law], it is highly unlikely that that state has any interest whatsoever in blanketing that particular issue with its law."[68]

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[66] *Boyes v. Greenwich Boat Works*, 27 F. Supp. 2d 543, 547 (D.N.J.1998); *see generally Weinberg v. Sprint Corp.*, 173 N.J. 233, 249, 801 A.2d 281 (2002) (stating that one legislative purpose behind creating a private right of action under the NJCFA was to "punish the wrongdoer through the award of treble damages").

[67] *Kalow & Springut LLP v. Commence Corp.*, 2012 WL 6093876, at *4 (D.N.J. Dec. 7, 2012) (quoting *DalPonte v. Am. Mortg. Express Corp.*, 2006 WL 2403982 (D.N.J. Aug. 16, 2006)).

[68] *Fu v. Fu*, 160 N.J. 108, 122-23 (1999); *Kalow*, 2012 WL 6093876, at *4 (applying *Fu* to the New Jersey CFA).

284. The New Jersey CFA makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby." N.J. Stat. Ann. § 56:8-2.

285. Sanofi and Plaintiffs are "persons" within the meaning of N.J. Stat. Ann. § 56:8-1(d).

286. Sanofi engaged in "sales" of "merchandise" within the meaning of N.J. Stat. Ann. § 56:8-1(c), (d).

287. As described above, through the Lantus Pricing Enterprise, Sanofi engaged in deceptive business practices prohibited by state consumer protection laws, including: inflating the stated benchmark price of Lantus; representing, affirmatively and through omission, that the Lantus benchmark price was the price of Lantus; concealing or misrepresenting the true price of Lantus and the existence and amount of the benchmark-to-real price spread amounting to a discount off the price of Lantus; and engaging in other unconscionable, false, misleading or deceptive acts or practices in the conduct of trade or commerce. Sanofi engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission, in connection with the pricing and sale of Lantus.

288. From the outset, Sanofi knew, but did not disclose, that the benchmark price it selected and published for Lantus did not reflect the true price of the product—it knew of the

substantial spread resulting in a windfall to the PBMs in exchange for the PBMs' agreement to grant Lantus exclusive or at least favorable placement on the formulary. Sanofi knew, but did not disclose, that the benchmark-to-real price spread did not result in a reduction in the prices paid by consumers who paid for all or part of their Lantus prescriptions out of pocket. Sanofi knowingly and deliberately misled consumers regarding the purpose, existence, and amount of price reductions off the Lantus benchmark price.

289. By failing to disclose and by actively concealing this pricing deceit, Sanofi engaged in unfair and deceptive business practices in violation of the New Jersey CFA. In the course of Sanofi's business, it willfully failed to disclose and actively concealed its misrepresentations regarding Lantus' price.

290. Sanofi intentionally and knowingly misrepresented material facts regarding the true price of Lantus with the intent to mislead consumers, including Plaintiffs. As alleged above, Sanofi, through the Lantus Pricing Enterprise, made material misstatements about the price of Lantus and the existence and extent of the Lantus benchmark-to-real price spread that were either false or misleading.

291. Sanofi owed Plaintiffs a duty to disclose the true price of Lantus and the existence of rebates off of Lantus' benchmark price because Sanofi:

a. Possessed exclusive knowledge about the means by which they selected the benchmark price for Lantus;

b. Knew material non-public information regarding the existence and amount of price reductions off of Lantus' benchmark price; and

c. Made incomplete representations about the price of Lantus, while purposefully withholding material facts from Plaintiffs that contradicted these representations.

292. Because Sanofi fraudulently concealed the true price of Lantus, Plaintiffs were deprived of the benefit of their bargain since they paid more than their pro-rata share of the

actual price of Lantus (*i.e.*, the price paid by PBMs after the artificially-inflated Lantus benchmark price was reduced by the rebates).

293. The truth about the actual price of these drugs, as distinguished from the inflated benchmark price, would be material to a reasonable consumer. So Sanofi's concealment of the Lantus pricing fraud was material to Plaintiffs. Had Plaintiffs been aware of the true price of Lantus, they would have demanded lower prices of Sanofi.

294. Sanofi's unfair or deceptive acts or practices were likely to and did in fact deceive reasonable consumers, including Plaintiffs, about the true price of Lantus.

295. Sanofi knew, or should have known, that its conduct violated state consumer protection laws.

296. As a direct and proximate result of Sanofi's violations of the New Jersey CFA, Plaintiffs have suffered injury-in-fact and/or actual damages. As a direct result of Sanofi's misconduct, all Plaintiffs incurred damages in at least the amount of money they paid out-of-pocket for Lantus.

297. This wrongful conduct by Sanofi, coupled with the damage insured by Plaintiffs and class members, entitles members of the class to relief under the New Jersey CFA. Plaintiffs are entitled to recover legal and/or equitable relief, including an order enjoining unlawful conduct, treble damages, costs, and reasonable attorneys' fees pursuant to N.J. Stat. Ann. § 56:8-19, and any other just and appropriate relief.

COUNT SIX: Violation Of The New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1 *et seq.* against Novo Nordisk

298. Plaintiffs repeat and incorporate by reference all preceding and succeeding paragraphs and allegations.

299. This claim is brought by Plaintiffs who paid for Levemir and Novolog, on behalf of all members of the Class. While Plaintiffs and class members hail from across the country, Novo Nordisk Inc. is a corporation with its headquarters in Plainsboro, New Jersey. New Jersey "has a powerful incentive to insure that local merchants deal fairly with citizens of other states and countries,"[69] and a "strong interest 'in regulating its domestic businesses and in deterring fraudulent business practices.'"[70] Furthermore, New Jersey has some of the strongest consumer protection laws in the country so, although other states may have some interest in protecting its own consumers, that interest is not frustrated by the application of New Jersey's law. "If a strong state policy or interest will [not be] frustrated by the failure to apply [that state's law], it is highly unlikely that that state has any interest whatsoever in blanketing that particular issue with its law."[71]

300. The New Jersey CFA makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby." N.J. Stat. Ann. § 56:8-2.

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[69] *Boyes v. Greenwich Boat Works*, 27 F. Supp. 2d 543, 547 (D.N.J.1998); *see generally Weinberg v. Sprint Corp.*, 173 N.J. 233, 249, 801 A.2d 281 (2002) (stating that one legislative purpose behind creating a private right of action under the NJCFA was to "punish the wrongdoer through the award of treble damages").

[70] *Kalow & Springut LLP v. Commence Corp.*, 2012 WL 6093876, at *4 (D.N.J. Dec. 7, 2012) (quoting *DalPonte v. Am. Mortg. Express Corp.*, 2006 WL 2403982 (D.N.J. Aug. 16, 2006)).

[71] *Fu v. Fu*, 160 N.J. 108, 122-23 (1999); *Kalow*, 2012 WL 6093876, at *4 (applying *Fu* to the New Jersey CFA).

301. Novo Nordisk and Plaintiffs are "persons" within the meaning of N.J. Stat. Ann. § 56:8-1(d).

302. Novo Nordisk engaged in "sales" of "merchandise" within the meaning of N.J. Stat. Ann. § 56:8-1(c), (d).

303. As described above, through the Levemir/Novolog Pricing Enterprise, Novo Nordisk engaged in deceptive business practices prohibited by state consumer protection laws, including: inflating the stated benchmark prices of Levemir and Novolog; representing, affirmatively and through omission, that the Levemir and Novolog benchmark prices were the prices of Levemir and Novolog; concealing or misrepresenting the true prices of Levemir and Novolog and the existence and amount of the benchmark-to-real price spread amounting to discounts off the prices of Levemir and Novolog; and engaging in other unconscionable, false, misleading or deceptive acts or practices in the conduct of trade or commerce. Novo Nordisk engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission, in connection with the pricing and sales of Levemir and Novolog.

304. From the outset, Novo Nordisk knew, but did not disclose, that the benchmark prices it selected and published for Levemir and Novolog did not reflect the true prices of the products—it knew of the substantial spread resulting in a windfall to the PBMs in exchange for the PBMs' agreement to grant Levemir and Novolog exclusive or at least favorable placements on the formulary. Novo Nordisk knew, but did not disclose, that the benchmark-to-real price spread did not result in a reduction in the prices paid by consumers who paid for all or part of Levemir and/or Novolog prescriptions out of pocket. Novo Nordisk knowingly and deliberately

misled consumers regarding the purpose, existence, and amount of price reductions off Levemir and Novolog's benchmark prices.

305. By failing to disclose and by actively concealing this pricing deceit, Novo Nordisk engaged in unfair and deceptive business practices in violation of the New Jersey CFA. In the course of Novo Nordisk's business, it willfully failed to disclose and actively concealed its misrepresentations regarding Levemir and Novolog's prices.

306. Novo Nordisk intentionally and knowingly misrepresented material facts regarding the true prices of Levemir and Novolog with the intent to mislead consumers, including Plaintiffs. As alleged above, Novo Nordisk, through the Levemir/Novolog Pricing Enterprise, made material misstatements about the prices of Levemir and Novolog and the existence and extent of the Levemir and Novolog benchmark-to-real price spreads that were either false or misleading.

307. Novo Nordisk owed Plaintiffs a duty to disclose the true prices of Levemir and Novolog and the existence of rebates off of Levemir and Novolog's benchmark prices because Novo Nordisk:

a. Possessed exclusive knowledge about the means by which it selected the benchmark prices for Levemir and Novolog;

b. Knew material non-public information regarding the existence and amount of price reductions off of Levemir and Novolog's benchmark price; and

c. Made incomplete representations about the prices of Levemir and Novolog, while purposefully withholding material facts from Plaintiffs that contradicted these representations.

308. Because Novo Nordisk fraudulently concealed the true price of Levemir and Novolog, Plaintiffs were deprived of the benefit of their bargain since they paid more than their pro-rata share of the actual prices of Levemir and Novolog (*i.e.*, the price paid by PBMs after the artificially-inflated Levemir and Novolog benchmark prices were reduced by the rebates).

309. The truth about actual prices of these drugs, as distinguished from the inflated benchmark prices, would be material to a reasonable consumer. So Novo Nordisk's concealment of the Levemir and Novolog pricing fraud was material to Plaintiffs. Had Plaintiffs been aware of the true prices of Levemir and Novolog, they would have demanded lower prices.

310. Novo Nordisk's unfair or deceptive acts or practices were likely to and did in fact deceive reasonable consumers, including Plaintiffs, about the true prices of Levemir and Novolog.

311. Novo Nordisk knew, or should have known, that its conduct violated state consumer protection laws.

312. As a direct and proximate result of Novo Nordisk's violations of the New Jersey CFA, Plaintiffs have suffered injury-in-fact and/or actual damages. As a direct result of Novo Nordisk's misconduct, all Plaintiffs incurred damages in at least the amount of money they paid out-of-pocket for Levemir and Novolog.

313. This wrongful conduct by Novo Nordisk, coupled with the damage insured by Plaintiffs and class members, entitles members of the class to relief under the New Jersey CFA. Plaintiffs are entitled to recover legal and/or equitable relief, including an order enjoining unlawful conduct, treble damages, costs and reasonable attorneys' fees pursuant to N.J. Stat. Ann. § 56:8-19, and any other just and appropriate relief.

COUNT SEVEN: Violation of the Florida Unfair and Deceptive Trade Practices Act, Fla. Stat. § 501.201 *et seq.* against all Defendants

314. Plaintiffs repeat and incorporate by reference all preceding and succeeding paragraphs and allegations.

315. This claim is brought by Plaintiffs on behalf of residents of Florida who are members of the Class.

316. The Florida Unfair and Deceptive Trade Practices Act ("FUDTPA") prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204(1).

317. Plaintiffs and class members are "consumers" within the meaning of Fla. Stat. § 501.203(7).

318. Each Defendant engaged in "trade or commerce" within the meaning of Fla. Stat. § 501.203(8).

319. Plaintiffs and Class Members are entitled to recover their actual damages under Fla. Stat. § 501.211(2) and attorneys' fees under Fla. Stat. § 501.2105(1).

320. Plaintiffs and the Class also seek an order enjoining each Defendant's unfair, unlawful, and/or deceptive practices, declaratory relief, attorneys' fees, and any other just and proper relief available under the FUDTPA.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed class, respectfully demand that this Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the class, and declare Plaintiffs as the representative of the class;

B. Enter judgments against Defendants and in favor of Plaintiffs and the class;

C. Award the class damages (i.e., three times overcharges) in an amount to be determined at trial;

D. Award Plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

E. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Plaintiffs, on behalf of themselves and others similarly situated, hereby request a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

Dated: February 13, 2017

Respectfully submitted,

/s/ James E. Cecchi

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